120.500: USE OF RADIONUCLIDES IN THE HEALING ARTS

General Information

120.501: Purpose and Scope

105 CMR 120.500 establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing ~~the medical use of this material~~ these activities. These requirements and provisions provide for the radiation safety of workers, the general public, ~~and~~ patients, and human research subjects. The requirements and provisions of 105 CMR 120.500 are in addition to, and not in substitution for, others in 105 CMR 120.000. The requirements and provisions of 105 CMR 120.000 apply to applicants and licensees subject to 105 CMR 120.500 unless specifically exempted. [See exemption in 105 CMR 120.104(C)(5)].

120.502: Definitions

As used in 105 CMR 120.500, the following definitions apply:

Address of use, means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

Area of Use, means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

Authorized medical physicist, means an individual who:

(1) Meets the requirements in 105 CMR 120.525 or 120.528; or

(2) Is identified as a medical physicist on a specific medical use license or equivalent permit issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State; or

(3) Is identified as a medical physicist on a permit issued by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State specific medical use license of broad scope that is authorized to permit the use of radioactive material.

Authorized Nuclear Pharmacist, means a pharmacist as defined in 105 CMR 120 005 who ~~is~~:

(1) ~~Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or~~ Meets the requirements in 105 CMR 120.526 or 120.528; or

(2) Is identified as an authorized nuclear pharmacist on a ~~NRC or Agreement State or Licensing State~~ specific license or equivalent permit that authorizes ~~the use of radioactive material in the practice of nuclear pharmacy~~ medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State; or

(3) Is identified as an authorized nuclear pharmacist on a permit issued by an Agency, ~~a~~ NRC or Agreement State or Licensing State specific licensee of broad scope that is authorized to permit the use of radioactive material ~~in the practice~~

~~of nuclear pharmacy~~; or

(4) Is a qualified nuclear pharmacist under 247 CMR 13.00

Authorized User, means a physician, dentist, or podiatrist who ~~is~~:

(1) Meets the requirements ~~Board certified by one of the boards listed~~ in 120.529, 120.546(A), 120.551(A), 120.556(A), 120.557(A), 120.558(A), 120.566(A), 120.567~~(A)~~, ~~120.568(A),~~ 120.569(A), or 120.587(A); ~~120.570(A), 120.572(A) or 120.573(A);~~

(2) Identified as an authorized user on a NRC or Agreement State or Licensing State license that authorizes the medical use of radioactive material; or

(3) Identified as an authorized user on a permit issued by an Agency, ~~a~~ NRC or Agreement State or Licensing State specific licensee of broad scope that is authorized to permit the medical use of radioactive material.

120.502: continued

Brachytherapy, means a method of radiation therapy in which ~~sealed~~ sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

Brachytherapy Source, means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's Address, means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with 105 CMR 120.541.

Dedicated Check Source, means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

Dentist, means an individual licensed by the Commonwealth to practice dentistry.

Diagnostic clinical procedures manual, means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

High dose-rate remote afterloader, means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

Low dose-rate remote afterloader, means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

Management, means the chief executive officer or ~~that individual's designee~~ other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

Manual brachytherapy, means a type of therapy in which brachytherapy sources are manually applied or inserted.

Medical Institution, means an organization in which several medical disciplines are practiced.

Medical Use, means the intentional internal or external administration of radioactive material~~,~~ or the radiation ~~therefrom,~~ from radioactive to patients or human research subjects under the supervision of an authorized user.

Medium dose-rate remote afterloader (MDR), means a device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the treatment site.

~~Misadministration, means the administration of:~~

~~(1) A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 µCi) of either sodium iodide I-125 or I-131:~~

~~(a) Involving the wrong patient or human research subject or wrong radio-pharmaceutical, or~~

~~(b) When both the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 1.11 megabecquerels (30 µCi).~~

~~(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:~~

~~(a) Involving the wrong patient or human research subject, wrong radiopharmaceutical, or wrong route of administration, or~~

~~(b) When the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage;~~

~~(3) A gamma stereotactic radiosurgery radiation dose:~~

~~(a) Involving the wrong patient or human research subject or wrong treatment site, or~~

~~(b) When the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose;~~

~~(4) A teletherapy radiation dose:~~

~~(a) Involving the wrong patient or human research subject, wrong mode of treatment, or wrong treatment site, or~~

~~(b) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose, or~~

~~(c) When the calculated weekly administered dose exceeds the weekly prescribed dose by 30% or more of the weekly prescribed dose, or~~

~~(d) When the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose;~~

~~(5) A brachytherapy radiation dose:~~

~~(a) Involving the wrong patient or human research subject, wrong radionuclide, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site), or~~

~~(b) Involving a sealed source that is leaking, or~~

~~(c) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure, or~~

~~(d) When the calculated administered dose differs from the prescribed dose by more than 20% of the prescribed dose;~~

~~(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 megabecquerels (30 μCi) of either sodium iodide I-125 or I-131, both:~~

~~(a) Involving the wrong patient or human research subject, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage, and~~

~~(b) When the dose to the patient or human research subject exceeds 50 millisieverts (5 rem) effective dose equivalent or 500 millisieverts (50 rem) dose equivalent to any individual organ.~~

Mobile ~~Nuclear Medicine~~ Medical Service, means the transportation ~~and medical use~~ of radioactive material and its medical use at the client's address.

Output, means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient intervention, means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Preceptor, means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

Prescribed dosage, means the quantity of a radiopharmaceutical activity as documented:

(1) In a written directive as specified in 105 CMR 120.521; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to 105 CMR 120.544, 120.547 and 120.552. ~~Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with~~

~~the directions of the authorized user for diagnostic procedures.~~

Prescribed dose, means:

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive; or

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive; or

(3) For manual brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive~~.~~; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed dose-rate remote afterloader, means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer, means an individual who:

(1) Meets the requirements in 105 CMR 120.524 or 120.528; or

(2) Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Agency for similar types and uses of radioactive material.

~~Recordable event, means the administration of:~~

~~(1) A radiopharmaceutical or radiation without a written directive where a written directive is required;~~

~~(2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;~~

~~(3) A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 µCi) of sodium iodide I-125 or I-131 when both the administered dosage differs from the prescribed dosage by more than 10% of the prescribed dosage, and the difference between the administered dosage and the prescribed dosage exceeds 555 kilobecquerels (15 µCi);~~

~~(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10% of the prescribed dosage;~~

~~(5) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15% or more of the weekly prescribed dose; or~~

~~(6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10% of the prescribed dose.~~

Sealed source, means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Sealed Source and Device Registry, means the national registry that contains all the registration certificates, generated by both Nuclear Regulatory Commission and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic radiosurgery, means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a dose to a tissue volume.

Structured educational program, means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy, as used in 105 CMR 120.500, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject. ~~therapeutic irradiation in which the source of radiation is at a distance from the body.~~

Temporary jobsite, means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Therapeutic dosage, means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose, means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

Treatment site, means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of use, means use of radioactive material as specified under 105 CMR 120.544, 120.547, 120.552, 120.559, 120.569, 120.570 or 120.589.

Unit dosage, means a dosage that:

(1) Is obtained or prepared in accordance with the regulations in 105 CMR 120.544, 120.547, 120.552; and,

(2) Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Visiting Authorized User, means an authorized user who is not identified on the license of the licensee being visited.

Written directive, means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in 105 CMR 120.521. ~~order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in 105 CMR 120.502 Written directive(6), containing the following information:~~

~~(1) For any administration of quantities greater than 1.11 megabecquerels (30 μCi) of sodium iodide I-125 or I-131: the dosage; or~~

~~(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration; or~~

~~(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose; or~~

~~(4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period; or~~

~~(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or~~

~~(6) For all other brachytherapy,~~

~~(a) prior to implantation: the radioisotope, number of sources, and source strengths; and~~

~~(b) after implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).~~

120.503: Maintenance of Records

Each record required by 105 CMR 120.500 must be legible throughout the retention period specified by each Agency regulation. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

120.504: Provisions for Research Involving Human Subjects

A licensee may conduct research involving human subjects using radioactive material provided:

(A) That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

(B) The research involving human subjects authorized in 120.504(A) shall be conducted using radioactive material authorized for medical use in the license; and

(C) Nothing in 105 CMR 120.504 relieves licensees from complying with the other requirements in 105 CMR 120.500.

(D) Nothing in 105 CMR 120.500 relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

120.505: Implementation

(A) A licensee shall implement the provisions in 105 CMR 120.500 on [insert effective date of the rule].

(B) When a requirement in 105 CMR 120.500 differs from the requirement in an existing license condition, the requirement in 105 CMR 120.500 shall govern.

(C) Any existing license condition that is not affected by a requirement in 105 CMR 120.500 remains in effect until there is a license amendment or license renewal.

(D) If a license condition exempted a licensee from a provision of 105 CMR 120.500 on [insert effective date of the rule], it will continue to exempt a licensee from the corresponding provision in 105 CMR 120.500.

(E) If a license condition cites provisions in 105 CMR 120.500 that will be deleted on [insert effective date of the rule], then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

(F) Licensees shall continue to comply with any license condition that requires it to implement procedures required by 105 CMR 120.573, 120.579, 120.580 and 120.581 until there is a license amendment or renewal that modifies the license condition.

120.50~~3~~ 6: License Required

(A) A ~~N~~o person shall only manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer radioactive material for medical use ~~except~~ in accordance with a specific license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, or as allowed in ~~pursuant to~~ 105 CMR 120.~~000~~ 506(B)(1) or(B)(2).

(B) (1) Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in 105 CMR 120.500 under the supervision of an authorized user as provided in 105 CMR 120.51~~0~~9.

(2) Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with the regulations in 105 CMR 120.500 under the supervision of an authorized nuclear pharmacist or an authorized user as provided in 105 CMR 120.51~~0~~9.

~~(C) Provisions for research involving human subjects. A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise a licensee shall apply for and receive approval of a specific amendment to its license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.~~

120.507: Application for License, Amendment~~s~~, or Renewal

(A) An application must be signed by the applicant's or licensee's management.

(B) An application for a license for medical use of radioactive material as described in 105CMR 120.544, 120.547, 120.552, 120.559, 120.568, 120.570 or 120.589 must be made by:

(1) Filing an original and one copy of Agency application form MRCP 120.100 - 4 that includes the facility diagram, equipment, and training, experience and qualifications of the Radiation safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s), and

(2) Submitting procedures required by sections 105 CMR 120.522, 120.531, 120.573, 120.579, 120.580 and 120.581, as applicable.

(C) A request for a license amendment or renewal must be made by:

(1) Submitting an original and one copy of either

(a) Agency form MRCP 120.100 - 4, or

(b) a letter requesting the amendment or renewal; and,

(2) Submitting procedures required by sections 105 CMR 120.522, 120.531, 120.573, 120.579, 120.580 and 120.581, as applicable.

(D) In addition to the requirements in 105 CMR 120507(A). and 120.507(C), an application for a license or amendment for medical use of radioactive material as described in 105 CMR 120.589 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in 105 CMR 120.501 through 120.543, as well as any specific information on:

(1) Radiation safety precautions and instructions;

(2) Training and experience of proposed users;

(3) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(4) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(E) The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.

(F) An applicant that satisfies the requirements specified in 105 CMR 120.127(B) may apply for a Type A specific license of broad scope.

120.50~~4~~8: License Amendment~~s~~

A licensee shall apply for and must receive a license amendment:

(A) ~~Before using radioactive material for a method or type of medical use not permitted by the license issued under 105 CMR 120.500;~~ Before it receives, prepares or uses radioactive material for a type of use that is permitted under 105 CMR 120.500, but that is not authorized on the licensee's current license issued pursuant to 105 CMR 120.500;

(B) Before permitting anyone, except a visiting authorized user, a visiting authorized medical physicist or visiting authorized nuclear pharmacist described in 105 CMR 120.511, to work as an authorized user, authorized medical physicist or an authorized nuclear pharmacist, respectively, under the license except an individual who is:

(1) for an authorized user, an individual who meets the requirements ~~certified by the organizations specified~~ in 105 CMR 120.529, 120.546(A), 120.551(A), 120.556(A), 120.557(A), 120.558(A), 120.566(A), 120.567~~(A)~~, ~~120.568(A),~~ 120.569(A), or 120.587(A); ~~120.570(A), 120.572(A) or 120.573(A);~~

(2) for an authorized nuclear pharmacist, an individual who meets the requirements ~~certified by the organization specified~~ in ~~105 CMR 120.580(A);~~ 105 CMR 120.526(A) and 120.529;

(3) for an authorized medical physicist, an individual who meets the requirements in 105 CMR 120.525(A) and 120.529;

(~~3~~4) identified as an authorized user, ~~or~~ an authorized nuclear pharmacist or authorized medical physicist on an Agency, or the U.S. Nuclear Regulatory Commission or Agreement State or Licensing State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or,

(~~4~~5) identified as an authorized user, ~~or~~ an authorized nuclear pharmacist or authorized medical physicist on a permit issued by the Agency, or the U.S. Nuclear Regulatory Commission or Agreement State or Licensing State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or the practice of nuclear pharmacy, respectively;

(C) Before changing a Radiation Safety Officer, except as provided in 105 CMR 120.515(C). ~~or Teletherapy Physicist~~;

(D) Before receiving radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;

(E) Before adding to or changing the areas of use ~~or address or addresses of use~~ identified in the application or on the license, except as specified in 105 CMR 120.509; ~~;~~ ~~and,~~

(F) Before changing the address(es) of use identified in the application or on the license;

(~~F~~G) Before changing statements, representations, and procedures which are incorporated into the license~~.~~; and,

(H) Before releasing licensed facilities for unrestricted use.

120.50~~5~~9: Notifications

(A) A licensee shall provide to the Agency a copy of the board certification, the Agency, NRC, Agreement State or Licensing State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to 105 CMR 120.50~~4~~8(B)~~(1) through 120.504(B)(4)~~.

(B) A licensee shall notify the Agency ~~in writing within~~ by letter no later than 30 days after: ~~when an authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or Teletherapy Physicist, permanently discontinues performance of duties under the license.~~

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee's mailing address changes;

(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 105 CMR 120.131(B); or,

(4) The licensee has added to or changed the areas where radioactive material is used in accordance with 120.544and 120.547.

~~120.506: ALARA Program~~

~~(A) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable (ALARA) as defined in 105 CMR 120.005.~~

~~(B) To satisfy the requirement of 105 CMR 120.506(A):~~

~~(1) The management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by 105 CMR 120.000 or the Radiation Safety Committee; or,~~

~~(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the Radiation Safety Officer.~~

~~(C) The ALARA program shall include an annual review by the Radiation Safety Committee for licensees that are medical institutions, or management and the Radiation Safety Officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.~~

~~(D) The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:~~

~~(1) A commitment by management to keep occupational doses as low as reasonably achievable;~~

~~(2) A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;~~

~~(3) Personnel exposure investigational levels as established in accordance with 105 CMR 120.508(B)(8) that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and,~~

~~(4) Personnel exposure action levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.~~

120.510: Exemptions Regarding Type A Specific Licenses of Broad Scope

A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

(A) The provisions of 105 CMR 120.507(D) regarding the need to file an amendment to the license for medical use of radioactive material as described in 105 CMR 120.589;

(B) The provisions of 105 CMR 120.508(B) regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or authorized medical physicist under the license;

(C) The provisions of 105 CMR 120.508(E) regarding additions to or changes in the areas of use at the addresses specified in the license;

(D) The provisions of 105 CMR 120.509(A) regarding notification to the Agency for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists; and,

(E) The provisions of 105 CMR 120.523(A) regarding suppliers for sealed sources.

120.511: License Issuance

(A) The Agency shall issue a license for the medical use of radioactive material if:

(1) The applicant has filed Agency application form MRCP 120.100 - 4 in accordance with the instructions in 105 CMR 120.507;

(2) The applicant has paid any applicable fee;

(3) The applicant meets the requirements of 105 CMR 120.100; and,

(4) The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety.

(B) The Agency shall issue a license for mobile services if the applicant:

(1) Meets the requirements in 105 CMR 120.511(A); and,

(2) Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with 105 CMR 120.527.

120.513: Specific Exemptions

The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in 105 CMR 120.500 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

~~120.507: Radiation Safety Officer~~

~~(A) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.~~

~~(B) The Radiation Safety Officer shall:~~

~~(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary;~~

~~(2) Implement written policy and procedures for:~~

~~(a) Authorizing the purchase of radioactive material;~~

~~(b) Receiving and opening packages of radioactive material;~~

~~(c) Storing radioactive material;~~

~~(d) Keeping an inventory record of radioactive material;~~

~~(e) Using radioactive material safely;~~

~~(f) Taking emergency action if control of radioactive material is lost;~~

~~(g) Performing periodic radiation surveys;~~

~~(h) Performing checks of survey instruments and other safety equipment;~~

~~(i) Disposing of radioactive material;~~

~~(j) Training personnel who work in or frequent areas where radioactive material is used or stored; and,~~

~~(k) Keeping a copy of all records and reports required by the Agency regulations, a copy of 105 CMR 120.000, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations; and,~~

~~(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the Agency for licensing action; or,~~

~~(4) For medical use sited at a medical institution, assist the Radiation Safety Committee in the performance of its duties.~~

~~120.508: Radiation Safety Committee~~

~~Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material.~~

~~(A) The Committee shall meet the following administrative requirements:~~

~~(1) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.~~

~~(2) The Committee shall meet at least once each calendar quarter.~~

~~(3) To establish a quorum and to conduct business, ½ of the Committees membership shall be present, including the Radiation Safety Officer and the management's representative.~~

~~(4) The minutes of each Radiation Safety Committee meeting shall include:~~

~~(a) The date of the meeting;~~

~~(b) Members present;~~

~~(c) Members absent;~~

~~(d) Summary of deliberations and discussions;~~

~~(e) Recommended actions and the numerical results of all ballots; and,~~

~~(f) Documentation of any reviews required in 105 CMR 120.506(C) and 120.508(B).~~

~~(5) The Committee shall provide each member with a copy of the meeting minutes, and retain one copy until the Agency authorizes its disposition.~~

~~(B) To oversee the use of licensed material, the Committee shall:~~

~~(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;~~

~~(2) Review, on the basis of safety and with regard to the training and experience standards of 105 CMR 120.500, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or Teletherapy Physicist before submitting a license application or request for amendment or renewal and before allowing an authorized user or authorized nuclear pharmacist to work under the license;~~

~~(3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;~~

~~(4) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the Agency for licensing action;~~

~~(5) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;~~

~~(6) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;~~

~~(7) Review annually, with the assistance of the Radiation Safety Officer, the radioactive material program; and,~~

~~(8) Establish a table of investigational and action levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.~~

~~120.509: Statement of Authorities and Responsibilities~~

~~(A) A licensee shall provide sufficient authority and organizational freedom to the Radiation Safety Officer and the Radiation Safety Committee to:~~

~~(1) Identify radiation safety problems;~~

~~(2) Initiate, recommend, or provide solutions; and,~~

~~(3) Verify implementation of corrective actions.~~

~~(B) A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer and the Radiation Safety Committee.~~

General Administrative Requirements

120.515: Authority and Responsibilities for the Radiation Protection Program

(A) In addition to the radiation protection program requirements of 105 CMR 120.210, a licensee's management must approve in writing:

(1) Requests for license application, renewal, or amendments before submittal to the Agency;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under 120.517.

(B) A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(C) For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 120.515(E), provided the licensee takes the actions required in 120.515(B),(D),(E) and (H). A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

(D) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(E) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(F) Licensees that are authorized for two or more different types of radioactive material use under 105 CMR 120.552, 120.559,

120.570, and 120.589, or two or more types of units under 120.571 shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

(G) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six months. The licensee shall maintain minutes of each meeting in accordance with 105 CMR 120.590(A).]

(H) A licensee shall retain a record of actions taken pursuant to 105 CMR 120.515(A), 120.515(B) and 120.515(D) in accordance with 120.590(A).

120.517: Radiation Protection Program Changes

(A) A licensee may revise its radiation protection program without Agency approval if:

(1) The revision does not require an amendment under 120.508;

(2) The revision is in compliance with the regulations and the license;

(3) The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and,

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(B) A licensee shall retain a record of each change in accordance with 105 CMR 120.590(B)

120.518: Duties of Authorized User and Authorized Medical physicist

120.51~~0~~9: Supervision

(A) A licensee ~~who~~ that permits the receipt, possession, ~~production, preparation, compounding,~~ use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 105 CMR 120.506(B)(1)~~3~~ shall:

(1) In addition to the requirements in 105 CMR 120.753, ~~I~~ instruct the supervised individual in the licensee's written ~~principles of~~ radiation protection procedures, written directive procedures, regulations of 105 CMR 120.500, and license conditions with respect to the use of radioactive material; ~~safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;~~

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of 105 CMR 120.500, and license conditions with respect to the medical use of radioactive material; and, ~~Periodically review the supervised individual's use of radioactive material, the records kept to reflect this use, and provide reinstruction as needed;~~

~~(3) Require an authorized user to be immediately available to communicate with the supervised individual; and,~~

(3 ~~4~~) Require that only those individuals permitted under state and local regulations and specifically trained, and

designated by the authorized user, be permitted to administer radionuclides or radiation to patients or human research subjects.

(B) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 105 CMR 120.506(C), shall: ~~shall require the supervised individual receiving, possessing, producing, preparing, compounding, using or transferring radioactive material under 105 CMR 120.503 to:~~

(1) Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and, ~~Follow the instructions of the supervising authorized nuclear pharmacist or user;~~

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, regulations of 105 CMR 120.500, and license conditions. ~~Follow the written radiation safety and quality management procedures established by the licensee; and,~~

~~(3) Comply with 105 CMR 120.000 and the license conditions with respect to the use of radioactive material.~~

(C) Unless physical presence as described in other sections of 105 CMR 120.500 is required, a licensee that permits supervised activities under 120.519(A) and 120.519(B) shall require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and able to be physically present within one hour of notification; and, ~~A licensee shall require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.~~

(D) A licensee that permits supervised activities under 120.519(A) and 120.519(B) is responsible for the acts and omissions of the supervised individual.

~~(D) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.~~

120.520 ~~11~~: Visiting Authorized User, ~~or~~ Visiting Authorized Nuclear Pharmacist or Visiting Medical Physicist

(A) A licensee may permit any visiting authorized user, ~~or~~ visiting authorized nuclear pharmacist or visiting authorized medical physicist to work as an authorized user, ~~use licensed material for medical use or in the practice of~~ authorized nuclear pharmacist ~~y~~ or medical physicist, respectively, under the terms of the licensee's license for 60 days each year if:

(1) The visiting authorized user, ~~or~~ the visiting authorized nuclear pharmacist or the visiting authorized medical physicist has the prior written permission of the licensee's management and, if the work is performed ~~use~~ ~~occurs~~ on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of an Agency, ~~[~~Agreement State, Licensing State or U.S. Nuclear Regulatory Commission~~]~~ license that identifies the visiting authorized user, ~~or~~ the visiting authorized nuclear pharmacist or the visiting authorized medical physicist by name as an authorized user for medical use, ~~or~~ as an authorized nuclear pharmacist, or as an authorized medical physicist respectively; and,

(3) Only those procedures for which the visiting authorized user ~~or the visiting authorized nuclear pharmacist~~ is specifically authorized by an Agency, ~~[~~Agreement State, Licensing State or U.S. Nuclear Regulatory Commission~~]~~ license are performed by that individual.

(B) A licensee need not apply for a license amendment in order to permit a visiting authorized user, ~~or~~ a visiting authorized nuclear pharmacist or a visiting authorized medical physicist to use licensed material as described in 105 CMR 120.520~~11~~(A).

(C) A licensee shall retain copies of the records specified in 105 CMR 120.5201~~1~~(A) ~~[for three years from the date of the last visit].~~ as specified in 105 CMR 120.590(A).

~~120.512: Mobile Nuclear Medicine Service Administrative Requirements~~

~~(A) The Agency shall license mobile nuclear medicine services and/or clients of such services. The mobile nuclear medicine service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile nuclear medicine service shall be licensed if the client receives or possesses radioactive material to be used by a mobile nuclear medicine service.~~

~~(B) Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's location for use by the mobile nuclear medicine service.~~

~~(C) A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use, unless the client has a license. Radioactive material delivered to the client's address of use shall be received and handled in conformance with the client's license.~~

~~(D) A mobile nuclear medicine service shall inform, a responsible individual, such as a representative of management or a Registered Nurse in charge of the patient or the Registered Nurse in charge of the nursing unit, who is on site at each client's address of use at the time that radiopharmaceuticals are being administered.~~

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~~120.513: Quality Management Program~~

~~(A) Each licensee shall establish and maintain a written quality management program to provide assurance that radioactive material or radiation therefrom will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:~~

~~(1) That, prior to administration, a written directive is prepared for:~~

~~(a) Any teletherapy radiation dose;~~

~~(b) Any gamma stereotactic radiosurgery radiation dose;~~

~~(c) Any brachytherapy radiation dose;~~

~~(d) Any administration of quantities greater than 1.11 megabecquerels (30 µCi) of either sodium iodide I-125 or I-131; or~~

~~(e) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I -125 or I-131;~~

~~[NOTE: If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user witin 48 hours of the oral revision. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the paitient's record and a written directive is prepared within 24 hours of the oral directive.]~~

~~(2) That, prior to each administration, the patient or human research subject's identity is verified by more than one method~~

as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(B) Each licensee shall:

(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of a representative sample of patient or human research subject administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of 105 CMR 120.513(A); and,

(3) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

(C) The licensee shall evaluate and respond to each recordable event, within 30 days after discovery of the recordable event, by:

(1) Assembling the relevant facts including the cause;

(2) Identifying what, if any, corrective action is required to prevent recurrence; and

(3) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

(D) Each licensee shall retain:

(1) Each written directive; and,

(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in 105 CMR 120.513(A)(1), in an auditable form, for three years after the date of administration.

(E) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

(F) (1) Each applicant for a new license shall submit to the Agency a quality management program as part of the application for a license and implement the program upon issuance of the license by the Agency.

(2) Each existing licensee, as applicable, shall submit a written certification that a quality management program has been implemented, unless such certification has been submitted to the NRC as part of an NRC license in effect prior to the effective date of the Agreement between the Commonwealth and the NRC under section 274b of the Atomic Energy Act of 1954, as amended (42 USC 2021). Each existing licensee shall retain a copy of the quality management program for review by the Agency.

120.514: Records, Notifications, and Reports of Misadministrations

(A) For a misadministration:

(1) The licensee shall notify the Agency by telephone no later than 24 hours after discovery of the misadministration.

(2) The licensee shall submit a written report to the Agency within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physicians's name; a brief description of the event; why the

event occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient or human research subject, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient or human research subject"), and if not, why not, and if the patient or human research subject was notified, what information was provided to the patient or human research subject. The report must not include the patient's or human research subject's name or other information that could lead to identification of the patient or human research subject.

(3) The licensee shall notify the referring physician and also notify the patient or human research subject of the misadministration not later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the patient or human research subject or that, based on medical judgement, telling the patient or human research subject would be harmful. The licensee is not required to notify the patient or human research subject without first consulting the referring physician. If the referring physician or patient or human research subject cannot be reached within 24 hours, the licensee shall notify the patient or human research subject as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient or human research subject, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the patient or human research subject was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient or human research subject by sending either:

(a) a copy of the report that was submitted to the Agency, or

(b) a brief description of both the event and the consequences, as they may affect the patient or human research subject, provided a statement is included that the report submitted to the Agency can be obtained from the licensee.

(B) Each licensee shall retain a record of each misadministration for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient or human research subject, and the patient's or human research subject's referring physician), the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(C) Aside from the notification requirement, nothing in 105 CMR 120.514(A) and (B) shall affect any rights or duties of licensees and physicians in relation to each other, patients, or human research subjects, or the patient's or the human research subject's responsible relatives or guardians.

120.515: Suppliers

A licensee shall use for medical use only:

(A) Radioactive material manufactured, produced, labeled, prepared, compounded, packaged, and distributed in accordance with a license issued pursuant to 105 CMR 120.000 or the equivalent regulations of another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission; and

(B) Reagent kits, radiopharmaceuticals, and/or radiobiologics that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration (FDA); or

(C) Radiopharmaceuticals compounded from a prescription in accordance with the regulations of the state Board of Pharmacy.

(D) Teletherapy and brachytherapy sources manufactured and distributed in accordance with a license issued pursuant to 105

~~CMR 120.000, or the equivalent regulations of another Agreement State, a Licensing State, or the NRC.~~

120.521 ~~13~~: Written Directives ~~Quality Management Program~~

(A) A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30 µCi), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

(B) The written directive must contain the patient or human research subject's name and the following:

(1) For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;

(2) For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;

(3) For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

(4) For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(5) For all other brachytherapy including LDR, MDR, and PDR:

(a) Prior to implantation: treatment site, the radionuclide, and dose; and,

(b) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose).

(C) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

(D) The licensee shall retain the written directive in accordance with 105 CMR 120.590(C).

120.522: Procedures for Administrations Requiring a Written Directive

(A) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and,

(2) Each administration is in accordance with the written directive.

(B) The procedures required by 105 CMR 120.522(A) must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 105 CMR 120.570.

120.523: Suppliers for Sealed Sources or Devices Containing Sealed Sources for Medical Use

For medical use, a licensee may only use:

(A) Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 105 CMR 120.100 or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State; or

(B) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 105 CMR 120.100 or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State.

120.524: Training for Radiation Safety Officer

Except as provided in 120.528, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in 120.515 to be an individual who:

(A) Is certified by a speciality board whose certification process includes all of the requirements in 120.524(B)(1). and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State, or;

(B) (1) Has completed a structured educational program consisting of both:

(a) 200 hours of didactic training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and,

5. Radiation dosimetry; and,

(b) One year of full time experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license that authorizes similar type(s) of use(s) of radioactive material involving the folloing:

1. Shipping, receiving and performing related radiation surveys;

2. Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;

3. Securing and controlling radioactive material;

4. Using administrative controls to avoid mistakes in the administration of radioactive material;

5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

6. Using emergency procedures to control radioactive material;

7. Disposing of radioactive material; and

(2) Has obtained written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 120.524(B)(1) and has achieved a level of radiation safety knowledge sufficient to independently function as an RSO for medical uses of radioactive material; or

(C) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities.

120.525: Training for Authorized Medical Physicist

The licensee shall require the authorized medical physicist to be an individual who:

(A) Is certified by a speciality board whose certification process includes all of the training and experience requirements in 120.525(B) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or

(B) (1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics, or an equivalent training program approved by the Agency, another Agreement State or the Nuclear Regulatory Commission and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time practical

experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in 105 CMR 120.536, 120.564(E),120.576, 120.577, 120.578, 120.579, 120.580, 120.581 and 120.583, as applicable; and,

(2) Has obtained written certification, signed by a preceptor authorized medical physicist, that the individual has satisfactorily completed the requirements in 120.525(B)(1) and has achieved a level of competency sufficient to independently function as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

120.526: Training for an Authorized Nuclear Pharmacist

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(A) Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in 120.526(B) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State ; or

(B) (1) Has completed 700 hours in a structured educational program consisting of both:

(a) Didactic training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and,

5. Chemistry of radioactive material for medical use; and,

(b) Supervised practical experience in a nuclear pharmacy involving:

1. Shipping, receiving, and performing related radiation surveys;

2. Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;

4. Using administrative controls to avoid misadministrations in the administration of radioactive material; and

5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in 120.526(B)(1) and has achieved a level of competency sufficient to function

independently as an authorized nuclear pharmacist.

120.528: Provisions for Experienced Radiation Safety Officer, Medical Physicist, Authorized User, and Nuclear Pharmacist

(A) An individual identified as a Radiation Safety Officer, a medical physicist, or a nuclear pharmacist on a Nuclear Regulatory Commission, an Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee that authorizes medical use or the practice of nuclear pharmacy, before [insert effective date of the rule] need not comply with the training requirements of 120.524, 120.525 and 120.526, respectively.

(B) Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of radioactive material on a Nuclear Regulatory Commission or Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee that authorizes medical use or the practice of nuclear pharmacy, issued before [insert effective date of the rule] who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556, 120.557, 120.558, 120.566, 120.567, 120.569 and 120.587.

120.529: Recentness of Training

The training and experience specified in 105 CMR 120.500 must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

General Technical Requirements

120.531~~16~~: Quality Control of Diagnostic Equipment

Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.

120.532~~17~~: Possession, Use, and Calibration~~,~~ of Instruments used to Measure the Activity of Unsealed Radioactive Material ~~and Check of Dose Calibrators~~

(A) For direct measurements performed in accordance with 120.534, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

(B) A licensee shall calibrate the instrumentation required in 120.532(A) in accordance with nationally recognized standards or the manufacturer's instructions.

(C) A licensee shall retain a record of each instrument calibration required by 120.532 in accordance with 105 CMR 120.5??

(A) A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject. In the case where the ionization type dose calibrator cannot be used effectively to verify administered activity, the licensee shall use an alternative method. Any alternative method to the use of a dose calibrator shall be approved by the Agency in writing. Any alternative method shall provide for acceptable verification of constancy, accuracy, linearity, and geometry dependence as applicable.

(B) Each licensee shall establish written quality control procedures for all dose calibrators used for measuring the amount of activity administered to a patient or human research subject, and shall have written procedures for the use of the instrumentation. As a minimum, quality control procedures and frequencies shall be those recommended by the American National Standards Institute in ANSI N42.13-1986 [or the licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. The check shall be done on a frequently used setting with a sealed source of not less than 1.85 megabecquerels (50 μCi) of any photon-emitting radionuclide with a half-life greater than 90 days;

(2) Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different radionuclides with activities of at least 1.85 megabecquerels (50 μCi) each. The activity of one source shall be determined by the manufacturer to be within 5% of the stated activity. All other sources used for this test shall be within 5% of the stated activity. All sources used to satisfy the accuracy test shall be calibration sources traceable to the National Institute of Standards and Technology (NIST) or other standards recognized as being equivalent by the NIST;

(3) Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 370 kilobecquerels (10 μCi) and the highest dosage that will be assayed; and,

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(C) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10% if the dosage is greater than 370 kilobecquerels (10 μCi) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10%.

(D) A licensee shall also perform checks and tests required by 105 CMR 120.517(B) following adjustment or repair of the dose calibrator.

(E) A licensee shall retain a record of each check and test required by 105 CMR 120.517 for three years. The records required by 105 CMR 120.517(B) shall include:

(1) For 105 CMR 120.517(B)(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For 105 CMR 120.517(B)(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the individual who performed the test;

(3) For 105 CMR 120.517(B)(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the individual who performed the test; and,

(4) For 105 CMR 120.517(B)(4), the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the individual who performed the test.

120.5331~~8~~: Calibration ~~and Check~~ of Survey Instruments

(A) A licensee shall ensure that the survey instruments used to show compliance with 105 CMR 120.200 and 120.500 have been calibrated before first use, annually, and following repair.

(B) To satisfy the requirements of 105 CMR 120.5 331~~8~~(A), the licensee shall:

(1) Calibrate all required scale readings up to ten millisieverts (1000 mrem) per hour with a radiation source;

(2) Have each radiation survey instrument calibrated:

(a) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

(b) FOR LINEAR SCALE INSTRUMENTS, AT TWO POINTS LOCATED APPROXIMATELY ONE-THIRD AND TWO-THIRDS OF FULL-SCALE ON EACH SCALE; FOR LOGARITHMIC SCALE INSTRUMENTS, AT MID-RANGE OF EACH DECADE, AND AT TWO POINTS OF AT LEAST ONE DECADE; AND FOR DIGITAL INSTRUMENTS, AT 3 POINTS BETWEEN 0.02 AND 10 MILLISIEVERTS (2 AND 1000 MREM) PER HOUR; AND

(c) FOR DOSE RATE INSTRUMENTS, SO THAT AN ACCURACY WITHIN PLUS OR MINUS 20 PERCENT OF THE TRUE RADIATION DOSE RATE CAN BE DEMONSTRATED AT EACH POINT CHECKED. ~~For each scale that shall be calibrated, calibrate two readings separated by at least 50% of scale rating; and,~~

(3) Conspicuously note on the instrument the ~~apparent dose rate from a dedicated check source as determined at the time of calibration, and the~~ date of calibration.

(C) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent. ~~To satisfy the requirements of 105 CMR 120.518(B), the licensee shall consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10%; and consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20% if a correction chart or graph is conspicously attached to the instrument.~~

~~(D) A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.~~

(E) The licensee shall retain a record of each survey instrument calibration in accordance with 105 CMR 120.5??. ~~required in 105 CMR 120.518(A) for three years. The record shall include:~~

~~(1) A description of the calibration procedure; and,~~

~~(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.~~

~~(F) To meet the requirements of 105 CMR 120.518(A), (B), and (C), the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by 105 CMR 120.518(E) shall be maintained by the licensee.~~

120.534 ~~19~~: Determination of Dosages of Unsealed Radioactive Material for Medical Use ~~Assay of Radiopharmaceutical Dosages~~

~~A licensee shall:~~

(A) A licensee shall determine and record the activity of each dosage prior to medical use. ~~Assay, before medical use, the activity of each radiopharmaceutical dosage that contains more than 370 kilobecquerels (10 µCi) of a photon-emitting radionuclide;~~

(B) For a unit dosage, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State. ~~Assay, before medical use, the activity of each radiopharmaceutical dosage emitting alpha and/or beta radiation as the radiation of principal interest, unless such radiopharmaceutical has been obtained:~~

~~(1) In unit dosage form, from a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or the equivalent requirements of the NRC or an Agreement State or Licensing State for individual patients or human research subjects; and,~~

~~(2) From a supplier which participates in a measurement quality assurance program with the National Institute of Standards and Technology, and which is designed to ensure that unit dosages have a calibration traceable to a national standard.~~

(C) For other than unit dosages, this determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State. ~~Retain a record of the assays or calibrations required by 105 CMR 120.519(A) and (B) for three years. To satisfy this requirement, the record shall contain the:~~

~~(1) radiopharmaceutical, or the radionuclide administered;~~

~~(2) Patient's or human research subject's name, and identification number if one has been assigned;~~

~~(3) Prescribed dosage and measured activity of the dosage at the time of assay, or a notation that the total activity was determined by a calibration traceable to a national standard;~~

~~(4) Date and time of the assay or calibration and the date and time of the administration; and,~~

~~(5) Initials of the individual who performed the assay or documentation of the supplier's participation in the measurement quality assurance program specified in 105 CMR 120.518(B).~~

(C) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.

(D) A licensee shall retain a record of the dosage determination required by 120.534 in accordance with 105 CMR 120.5??

120.535 ~~20~~: Authorization for Calibration, Transmission and Reference Sources

Any person authorized by 105 CMR 120.503 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

(A) Sealed sources manufactured and distributed by persons specifically licensed pursuant to 105 CMR 120.128(L) ~~00~~ or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 1.11 ~~0~~ gigabecquerels (30 ~~27.2~~ mCi) each;

(B) Any radioactive material with a half-life of 120 ~~0~~ days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);

(C) Any radioactive material with a half life greater than 120 ~~0~~ days in individual amounts not to exceed the smaller of 7.4 megabecquerels (200 µCi) or 1000 times the quantity in TableI of 120.196: Appendix B ~~each~~; and,

(D) Technetium-99m in ~~individual~~ amounts as needed. ~~not to exceed 1.85 gigabecquerels (50 mCi).~~

120.536 ~~21~~: Requirements for Possession of Sealed Sources and Brachytherapy Sources

(A) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency ~~and shall maintain the instructions for the duration of source use in a legible form convenient to users~~.

(B) A licensee in possession of a sealed source shall ~~assure that~~:

(1) Test ~~T~~ the source ~~is tested~~ for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and,

(2) Test ~~T~~ the source ~~is tested~~ for leakage at intervals not to exceed six months or at intervals approved by the Agency, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.

(C) To satisfy the leak test requirements of 105 CMR 120.536 ~~21~~(B), the licensee shall measure the sample so that the leak test can detect the presence of 185 becquerels (0.005 µCi) of radioactive material in the sample. ~~assure that:~~ If the leak test reveals the presence of 185 becquerels (0.005 µCi) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store, repair or dispose of it in accordance with the requirements of 105 CMR 120.100 and 120.200; and,

(2) File a report with the Agency within five days of receiving the leak test results with the Agency describing the equipment involved, the test results, and the action taken.

~~(1) Leak tests are capable of detecting the presence of 185 becquerels (0.005 µCi) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 37 becquerels (0.001 µCi) per 24 hours;~~

~~(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and,~~

~~(3) Test samples are taken when the device containing the source is in the "off" position.~~

(D) A licensee shall retain leak test records in accordance with 105 CMR 120.590(I)(1).

~~(D) A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in becquerels (µCi), a description of the method used to measure each test sample, the date of the test, and the signature of the individual who performed the test~~.

~~(E) If the leak test reveals the presence of 185 becquerels (0.005 µCi) or more of removable contamination, the licensee shall:~~

~~(1) Immediately withdraw the sealed source from use and store, repair or dispose of it in accordance with the requirements of 105 CMR 120.200; and,~~

~~(2) File a report with the Agency within five days of receiving the leak test results with the Agency describing the~~

~~equipment involved, the test results, and the action taken~~.

~~(F) A licensee need not perform a leak test on the following sources:~~

~~(1) Sources containing only radioactive material with a half-life of less than 30 days;~~

~~(2) Sources containing only radioactive material as a gas;~~

~~(3) Sources containing 3.7 megabecquerels (100 µCi) or less of beta or photon-emitting material or 370 kilobecquerels (10 µCi) or less of alpha-emitting material;~~

~~(4) Seeds of iridium-192 encased in nylon ribbon; and,~~

~~(5) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.~~

(E~~G~~) A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. ~~at intervals not to exceed three months.~~ The licensee shall retain each inventory record in accordance with 105 CMR 120.590(I)(2). ~~for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the individual who performed the inventory.~~

~~(H) A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.~~

~~(I) A licensee shall retain a record of each survey required in 105 CMR 120.521(H) for three years. The record shall include the date of the survey, a sketch of each area that was surveyed, and the measured dose rate at several points in each area expressed in microsieverts (mrem) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the individual who performed the survey.~~

120.537 ~~22~~: Labeling of Vials and Syringes

Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

~~120.522: Syringe Shields~~

~~(A) A licensee shall keep syringes that contain radioactive material to be administered in an appropriate radiation shield or shielded area.~~

~~(B) A licensee shall require each individual who prepares or administers radiopharmaceuticals to use an appropriate syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.~~

~~120.523: Syringe Labels~~

~~A licensee shall conspicuously identify each syringe, or syringe radiation shield as to contents or intended patient or human research subject.~~

~~120.524: Vial Shields~~

~~A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.~~

~~120.525: Vial Shield Labels~~

~~A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.~~

120.539 ~~26~~: Surveys for Ambient Radiation Dose Rate and Contamination

(A) In addition to the surveys required by 105 CMR 120.200, a ~~A~~ licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed radioactive material requiring a written directive ~~radiopharmaceuticals~~ was ~~are~~ prepared for use or administered.

(B) A licensee does not need to perform the surveys required in 120.539(A) in area(s) where patients or human research subjects are confined when they can not be released pursuant to 120.540.

(C) A licensee shall retain a record of each survey in accordance with 120.5??

~~(B) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.~~

~~(C) A licensee shall conduct the surveys required by 105 CMR 120.526(A) and (B) so as to be able to measure dose rates as low as 1.0 microsievert (0.1 mrem) per hour.~~

~~(D) A licensee shall establish dose rate action levels for the surveys required by 105 CMR 120.526(A) and (B) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.~~

~~(E) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.~~

~~(F) A licensee shall conduct the surveys required by 105 CMR 120.526(E) so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm).~~

~~(G) A licensee shall establish removable contamination action levels for the surveys required by 105 CMR 120.526(E) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.~~

~~(H) A licensee shall retain a record of each survey required by 105 CMR 120.526(A), (B), and (E) for three years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in microsieverts (mrem) per hour or the removable contamination in each area expressed in becquerels (dpm) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.~~

120.540 ~~27~~: Release of Individuals ~~Patients or Human Research Subjects~~ Containing Unsealed Radioactive Material or Implants Containing Radioactive Material ~~Radiopharmaceuticals or Permanent Implants~~

(A) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (0.5 rem). [NOTE: NRC Regulatory Guide, NUREG-1566, Vol. 9, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding five millisieverts (0.5 rem).]

(B) For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and,

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(C) The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 120.590(K)(1).

(D) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with 120.590(K)(2).

(E) The licensee shall immediately notify the Agency in accordance with 120.590(D) if a patient departs prior to an authorized release.

~~(A) Unless otherwise authorized pursuant to 105 CMR 120.527(C), a licensee shall not authorize release from confinement for medical care any individual administered a radiopharmaceutical until either:~~

~~(1) The dose rate from the individual is less than 50 microsieverts (5mrem) per hour at a distance of one meter; or,~~

~~(2) The activity in the individual is less than 1.11 gigabecquerel (30 mCi).~~

~~(B) Unless otherwise authorized pursuant to 105 CMR 120.527(C), a licensee shall not authorize release from confinement for medical care any individual administered a permanent implant until the dose rate from the individual is less than 50 microsieverts (5mrem) per hour at a distance of one meter.~~

~~(C) A licensee may apply to the Agency for approval of proposed procedures, not otherwise authorized in 105 CMR 120.000, to release from its control individuals who have been administered radiopharmaceuticals or permanent implants containing radioactive material. Each application shall include:~~

~~(1) An analysis and evaluation of pertinent information to show that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisieverts (0.5 rem);~~

~~[NOTE: NRC Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding five millisieverts (0.5 rem).]~~

~~(2) A copy of the instructions, including written instructions, to be provided to the released individual on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one millisievert (0.1 rem).~~

120.5412~~8~~: Provision of Mobile ~~Nuclear Medicine~~ Medical Service ~~Technical Requirements~~

The Agency may license mobile medical services and/or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

(A) A licensee providing mobile medical service shall:

(1) Obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use and clearly delineates the authority and responsibility of the licensee and the client. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's location for use by the mobile medical service;

(2) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by 120.541(A)(2) must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and,

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in 105 CMR 120.200.

(B) A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(C) A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

(D) A mobile medical service licensee shall maintain all records required by 105 CMR 120.200 and 120.500 at a location within the Agency's jurisdiction that is:

(1) A single address:

(a) identified as the records retention location; and,

(b) staffed at all reasonable hours by individual(s) authorized to provide the Agency with access for purposes of inspection; or

(2) When no address is identified on the license for records retention, the mobile unit:

(a) identified in the license; and,

(b) whose current client's address schedule and location schedule is reported to the Agency.

(E) A licensee providing mobile medical services shall:

(1) Retain the letter required in 105 CMR 120.541(A)(1) in accordance with 105 CMR 120.597; and,

(2) Retain a record of each survey required by 105 CMR 120.541(A)(4) in accordance with 105 CMR 120.597.

~~A licensee providing mobile nuclear medicine service shall:~~

~~(A) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;~~

~~(B) Bring into each area of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;~~

~~(C) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an area of use;~~

~~(D) In addition to complying with 105 CMR 120.517 and 120.518, check survey instruments and dose calibrators for constancy and response, and check all other transported equipment for proper function before medical use at each area of use;~~

~~(E) Carry a survey meter calibrated in accordance with 105 CMR 120.518 in each vehicle that is being used to transport radioactive material, and, before leaving a client area of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed;~~

~~(F) Retain a record of each survey required by 105 CMR 120.528(E) for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in microsieverts (mrem) per hour, any removable contamination expressed in becquerels (dpm) per 100 square centimeters, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey; and,~~

(~~G~~E) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Agency for compliance with airborne release standards.

120.5~~29~~42: Storage of Volatiles and Gases

(A) A licensee shall store volatile radiopharmaceuticals and radioactive gases in a ~~the shippers'~~ radiation shield and container.

(B) A licensee shall store and use a multidose container in a properly functioning fume hood.

(C) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in 105 CMR 120.200.

(D) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay

or disposal of the aerosol or gas in a shielded container.

(E) A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for 3 years.

120.543 ~~30~~: Decay-In-Storage

~~A licensee may hold radioactive material for decay-in-storage if the material has a physical half-life of less than 65 days or, if the Agency has approved it, material of longer half-life.~~

(A) A licensee may hold radioactive material with a physical half-life of less than 120 days (or longer, if the Agency has approved it) for decay-in-storage before disposal without regard to its radioactivity if the licensee: ~~Before disposal in ordinary trash, a licensee shall hold radioactive material for decay-in-storage and is exempt from the waste disposal requirements of 105 CMR 120.200 if the licensee:~~

~~(1) Holds radioactive material for decay a minimum of ten half-lives;~~

(1 ~~2~~) Monitors radioactive material at the ~~container~~ surface ~~before disposal as ordinary trash~~ and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(2 ~~3~~) Removes or obliterates all radiation labels except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and,

(3 ~~4~~) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

(B) For radioactive material disposed in accordance with 105 CMR 120.530(A), the licensee shall retain a record of each disposal in accordance with 120.5??. ~~for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.~~

Specific Requirements for the Use of Radioactive Material for Uptake, Dilution, or Excretion Studies

120.544 ~~31~~: Use of Unsealed Radioactive Material ~~Radiopharmaceuticals~~ for Uptake, Dilution, or Excretion Studies for which a Written Directive is Not Required

A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, ~~a radiopharmaceutical~~ for a diagnostic use involving measurements of uptake, dilution, or excretion:

(A) Obtained from a manufacturer or preparer licensed pursuant to 105 CMR 120 128(J) or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or ~~which has been granted acceptance or approval by the FDA; or~~,

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 105 CMR 120.546, 105 CMR 120.551, or an individual under the supervision of either as specified in 105 CMR 120.519; or ~~which is prepared and compounded in accordance with the regulations of the state Board of Pharmacy by an authorized nuclear pharmacist, an authorized user physician who meets the requirements of 105 CMR 120.567, or an individual~~

~~supervised by either pursuant to 105 CMR 120.510.~~

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

120.545 ~~32~~: Possession of Survey Instrument

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 1000 microsieverts (100 mrems) per hour. The instrument shall be operable and calibrated in accordance with 105 CMR 120.533 ~~18~~.

120.546: Training for Uptake, Dilution, and Excretion Studies

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 120.544 to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 120.546(C). and whose certification has been recognized by the Nuclear Regulatory Commission, or an Agreement State; or

(B) Is an authorized user under 105 CMR 120.551 or 105 CMR 120.556, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C)(1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes:

(a) Classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and,

5. Radiation biology; and,

(b) Work experience, under the supervision of an authorized user who meets the requirements 105 CMR 120

546,120.551 or 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and,

6. Administering dosages to patients or human research subjects; and,

(2) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120 546, 120.551 or 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120 546(C)(1) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120 544.

Specific Requirements for the Use of Unsealed Radioactive Material - Written Directive Not Required

120.547 ~~33~~: ~~Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies~~ Use of Unsealed Radioactive Material for Imaging and Localization Studies for which a Written Directive is Not Required

A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in 105 CMR 120.521 that is: ~~in a diagnostic radiopharmaceutical (except aerosol or gaseous forms) or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material:~~

(A) Obtained from a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; ~~or which has been granted acceptance or approval by the FDA;~~ or

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements

specified in 105 CMR 120.551 or 120.556, or an individual under the supervision of either as specified in 120.519; or ~~which has been prepared and compounded in accordance with the regulations of the state Board of Pharmacy by an authorized nuclear pharmacist, an authorized user physician who meets the requirements of 105 CMR 120.568, or an individual supervised by either pursuant to 105 CMR 120.510.~~

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or ~~A licensee shall elute generators in compliance with 105 CMR 120.534.~~

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

(E~~D~~) Provided the conditions of 105 CMR 120.542 ~~35~~ are met, a licensee may use radioactive aerosols or gases if specific application is made to and approved by the Agency.

120.548 ~~34~~: Radionuclide Contaminants

(A) A licensee shall not administer to humans a radiopharmaceutical containing**:**

(1) more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 µCi of Mo-99 per mCi of Tc-99m);

(2) more than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 µCi of Sr-82 per mCi of Rb-82 chloride);

(3) more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 µCi of Sr-85 per mCi of Rb-82).

(B) To demonstrate compliance with 105 CMR 120.548(A), the licensee preparing radioactive drugs from radionuclide generators shall: ~~A licensee preparing radiopharmaceuticals from radionuclide generators shall measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for the generator system, to determine compliance with the limits specified in 105 CMR 120.55134(A).~~

(1) Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;

(2) Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

(C) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with 105 CMR 120 5??. ~~for three years. The record shall include, for each elution or extraction tested, the measured activity of the radiopharmaceutical expressed in megabecquerels (mCi), the measured activity of contaminat expressed in kilobecquerels (µCi), the ratio of the measures expressed as kilobecquerels (µCi) contaminant per megabecquerel (mCi) radiopharmaceutical, the date of the test, and the initials of the individual who performed the test.~~

(D) A licensee shall report immediately to the Agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in 105 CMR 120.548 ~~34~~(A).

120.552 ~~35~~: Reserved ~~Control of Aerosols and Gases~~

~~(A) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in 105 CMR 120.200.~~

~~(B) The system shall [either be directly vented to the atmosphere through an air exhaust or] provide for collection and decay or disposal of the aerosol or gas in a shielded container.~~

~~(C) A licensee shall only administer radioactive gases in rooms that are at negative pressure with respect to surrounding rooms.~~

~~(D) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in 105 CMR 120.296. *Appendix* B. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.~~

~~(E) A licensee shall post the time calculated in 105 CMR 120.535(D) at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.~~

~~(F) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.~~

~~(G) A copy of the calculations required in 105 CMR 120.535(D) shall be recorded and retained for the duration of the license.~~

~~120.536: Possession of Survey Instruments~~

~~A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one microsievert (0.1 mrem) per hour to 1000 microsieverts (100 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsieverts (one mrem) per hour to ten millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with 105 CMR 120.518.~~

120.551: Training for Imaging and Localization Studies

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 105 CMR 120.547 to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 120.551(C). and whose certification has been recognized by the Nuclear Regulatory Commission, or an Agreement State; or

(B) Is an authorized user under 105 CMR 120.556, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies; the training and experience must include, at a minimum:

(a) Classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use;

5. Radiation biology; and,

(b) Work experience, under the supervision of an authorized user who meets the requirements 105 CMR 120 551 or 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and,

6. Administering dosages of radioactive drugs to patients or human research subjects; and,

(2) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.551 or 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120 551(C)(1) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120 544 and 120.547

Specific Requirements for the Use of Unsealed Radioactive Material - Written Directive Required.

120.5523~~7~~: Use of Unsealed Radioactive Material for which a Written Directive is Required ~~Radiopharmaceuticals for Therapy~~

A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been: ~~in a radiopharmaceutical and for a therapeutic use:~~

(A) Obtained from a manufacturer or preparer licensed in accordance with 105 CMR 120128(J); or ~~which has been granted acceptance or approval by the FDA; or,~~

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551 or 105 CMR 120.556, or an individual under the supervision of either as specified in 105 CMR 120 519; or ~~which has been prepared and compounded in accordance with the regulations of the state Board of Pharmacy by~~

~~an authorized nuclear pharmacist, an authorized user physician who meets the requirements of 105 CMR 120.569, or an individual supervised by either pursuant to 105 CMR 120.510.~~

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

120.553 ~~38~~: Safety Instruction

In addition to the requirements of 105 CMR 120.753:

(A) A licensee shall provide ~~oral and written~~ radiation safety instruction, initially and at leastannually, to ~~for all~~ personnel caring for patients or human research subjects who have received therapy with with a radioactive drug, and cannot be released in accordance with 105 CMR 120.540. ~~undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed one year.~~ To satisfy the requirement in 105 CMR 120.553(A), the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control to include the following:

(a) Routine visitation to hospitalized individuals in accordance with 105 CMR 120.221(A)(1) and 120.221(C);

(b) Contamination control;

(c) Waste control; and,

(d) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

(B) A licensee shall retain a record of individuals receiving instruction in accordance with 105 CMR 120.5??

~~(B) To satisfy 105 CMR 120.538(A), the instruction shall describe the licensee's procedures for:~~

~~(1) Patient or human research subject control;~~

~~(2) Visitor control;~~

~~(3) Contamination control;~~

~~(4) Waste control;~~

~~(5) Notification of the Radiation Safety Officer or authorized user in case of the patient's or human research subject's death or medical emergency; and~~

~~(6) Training for workers as required by 105 CMR 120.750.~~

~~(C) A licensee shall keep a record of individuals receiving instruction required by 105 CMR 120.538(A), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the Agency for three years.~~

120.5543~~9~~: Safety Precautions

(A) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 105 CMR 120.540 ~~27~~, a licensee shall:

(1) ~~Provide a private room with a private sanitary facility;~~ Quarter the patient or the human research subject either in:

(a) A private room with a private sanitary facility; or

(b) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with 105 CMR 120.540; and,

(2) Visibly ~~P~~ post the patient's or human research subject's door with a "~~Caution~~: Radioactive Materials" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and,

~~(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;~~

~~(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 105 CMR 120.200 and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;~~

(~~5~~ 3) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste~~;~~.

~~(6) Instruct the patient or human research subject and, where appropriate, the patient's or human research subject's family, orally and in writing concerning radiation safety precautions that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or human research subject;~~

~~(7) Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 3.33 becquerels (200 dpm) per 100 square centimeters; and,~~

~~(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by 105 CMR 120.200 a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements. Other procedures acceptable to the Agency may be used for individuals who only prepare, but do not administer, doses of stabilized I-131.~~

~~(B) For each non-hospitalized patient or human research subject receiving radiopharmaceutical therapy, the licensee shall instruct the patient or human research subject and, where appropriate, the patient's or human research subject's family, orally and in writing concerning radiation safety precautions that will help to keep radiation doses to the household members and the public as low as reasonably achievable.~~

(~~C~~B) The Radiation Safety Officer, or his or her designee, and ~~or~~ the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

~~120.540: Possession of Survey Instruments~~

~~A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 1000 microsievert (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsieverts (one mrem) per hour to ten millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with 105 CMR 120.518.~~

120.556: Training for Use of Unsealed Radioactive Material for which a Written directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of radioactive material for the uses authorized under 105 CMR 120.552 to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 120.556(B). and whose certification has been recognized by the Nuclear Regulatory Commission, or an Agreement State; or

(B)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive, that includes:

(a) Classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use;

5. Radiation biology; and,

(b) Work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.556 or or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

6. Administering dosages to patients or human research subjects; and,

7. Eluting generator systems, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs containing radioactive material; and

(2) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of 3 cases in each of the following categories for which the individual is requesting authorized user status. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.556(B)(1)(b):

(a) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

(b) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 [Note: *Experience with at least three cases of in category (b) also satisfies the requirement in category (a)]*;

(c) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(d) Parenteral administration of any other radionuclide; and,

(3) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements 105 CMR 120.556(B)(1) and 105 CMR 120.556(B)(2) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120.556. The preceptor authorized user, who meets the requirements of 105 CMR 120.556(B) must have experience in administering dosages in the same dosage category or categories listed in 105 CMR 120.556(B)(2) as the individual requesting authorized user status.

120.557: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabequerels (33 millicurie) for which a Written directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.557(C) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or

(B) Is an authorized user under 105 CMR 120.556(A), 120.556(B), for uses listed in 120.556(B)(2)(a) or (b), 120.558 or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C)(1) Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and,

(e) Radiation biology; and,

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.556(A), 120.556(B), 120.557 or120.558, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of 120.556(B) must have experience in administering dosages as specified in 120.556(B)(2)(a) or 120.556(B)(2)(b); the work experience must involve:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(f) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in 120.557(C)(1) and 120.557(C)(2), and has achieved a level of competency sufficient to independently function as an authorized user for medical uses of unsealed radioactive material using sodium iodide I-131. The written certification must be signed by a preceptor authorized user, who meets the requirements of 120.556(A), 120.556(B), 120.557 or 120.558, or equivalent Agreement State or Nuclear Regulatory Commission requirements. The preceptor authorized user who meets the requirements of 120.556(B) must have experience in administering dosages as specified in 120.556(B)(2)(a) and/or (b).

120.558: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabequerels (33 millicurie) for which a Written Directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.557(C) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or

(B) Is an authorized user under 105 CMR 120.556(A), 120.556(B), for uses listed in 120.556(B)(2)(b), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or

(C)(1) Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and,

(e) Radiation biology; and,

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.556(A), 120.556(B), 120.557 or120.558, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of 120.556(B), must have experience in administering dosages as specified in 120.556(B)(2)(b); the work experience must involve:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(f) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in 120.558(C)(1) and 120.558(C)(2), and has achieved a level of competency sufficient to independently function as an authorized user for medical uses of unsealed radioactive material using sodium iodide I-131 in activities greater than 1.22 gigabecquerels (33 millicuries). The written certification must be signed by a preceptor authorized user, who meets the requirements of 120.556(B), 120.558, or equivalent Agreement State or Nuclear Regulatory Commission requirements. The preceptor authorized user who meets the requirements of 120.556(B) must have experience in administering dosages as specified in 120.556(B)(2)(b).

Manual Brachytherapy

120.559 ~~43~~: Use of Sealed Sources for Manual Brachytherapy

A licensee shall use only brachytherapy sources for therapeutic medical uses ~~the following sources in accordance with the manufacturer's radiation safety and handling instructions~~:

(A) As approved in the Sealed Source and Device Registry; or

(B) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 105 CMR 120.523(A). are met.

~~(A) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~

~~(B) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~

~~(C) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;~~

~~(D) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;~~

~~(E) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;~~

~~(F) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and~~

~~(G) Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.~~

120.560: Surveys After Source Implant and Removal

(A) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

(B) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(C) A licensee shall retain a record of the surveys in accordance with 105 CMR 120.5??.

120.561: Brachytherapy Sources Accountability

(A) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(B) Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(C) A licensee shall maintain a record of the brachytherapy source accountability in accordance with 105 CMR 120.5??

120.562 ~~44~~: Safety Instruction

In addition to the requirements of 105 CMR 120.753:

(A) The licensee shall provide ~~oral and written~~ radiation safety instruction, initially and at least annually, to ~~all~~ personnel caring for ~~a~~ patients or human research subjects that are undergoing ~~receiving~~ implant therapy and cannot be released in accordance with 105 CMR 120 540. Instruction must be commensurate with the duties of the personnel and shall include the following: ~~Refresher training shall be provided at intervals not to exceed one year.~~

~~(B) To satisfy 105 CMR 120.544(A), the instruction shall describe:~~

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions ~~in case of a dislodged source~~;

(3) ~~Procedures for p~~ Patient or human research subject control;

(4) ~~Procedures for v~~ Visitor control, including both: ~~; and,~~

(a) Routine visitation of hospitalized individuals in accordance with 105 CMR 120.221(A)(1) of these regulations; and

(b) Visitation authorized in accordance with 105 CMR 120.221(C) of these regulations; and

(5) ~~Procedures for n~~ Notification of the Radiation Safety Officer, or his or her designee, ~~or~~ and an authorized user if the patient or human research subject dies or has a medical emergency.

(6) A licensee shall retain a record of individuals receiving instruction in accordance with 105 CMR 120.5??. ~~Training for workers as required by 105 CMR 120.750.~~

~~(C) A licensee shall maintain a record of individuals receiving instruction required by 105 CMR 120.544(A), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.~~

120.563 ~~45~~: Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy

(A) For each patient or human research subject receiving ~~implant~~ brachytherapy therapy and cannot be released in accordance with 105 CMR 120.540, a licensee shall:

(1) Not place the patient or human research subject in the same room ~~with a patient~~ as an individual who is not receiving ~~radiation~~ brachytherapy therapy ~~unless the licensee can demonstrate compliance with the radiation dose limits for individual members of the public as specified in 105 CMR 120.200 at a distance of one meter from the implant~~;

(2) Visibly ~~P~~ post the patient's or human research subject's door with a ~~"Caution:~~ "Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

~~(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;~~

~~(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 105 CMR 120.200 and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and,~~

~~(5) Before authorizing the release of a patient or human research subject administered a permanent implant, instruct the patient or human research subject, and where appropriate, the patient's or human research subject's family, orally and in writing concerning radiation safety precautions that will help keep the radiation dose to household members and the public as low as reasonably achievable .~~

(B) A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

(1) Dislodged from the patient; or

(2) Lodged within the patient following removal of the source applicators.

(C ~~B~~) The Radiation Safety Officer, or his or her designee, and the ~~or~~ authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

120.564 ~~46~~: Calibration Measurement of Brachytherapy Sealed Sources ~~Inventory~~

(A) Prior to the first medical use of a brachytherapy sealed source on or after [insert effective date of the rule], a licensee shall perform the following:

(1) Determine the source output or activity using a dosimetry system that meets the requirements of 105 CMR 120.575(A);

(2) Determine source positioning accuracy within applicators; and

(3) Use published protocols accepted by nationally recognized bodies to meet the requirements of 105 CMR 120.564(A)(1) and 105 CMR 120.564(A)(2).

(B) A licensee may use measurements provided by the source manufacturer [or by a calibration laboratory accredited by the American Association of Physicists in Medicine] that are made in accordance with 105 CMR 120.564(A).

(C) A licensee shall mathematically correct the outputs or activities determined in 105 CMR 120.564(A)of this section for physical decay at intervals consistent with 1.0 percent physical decay.

(D) An authorized medical physicist shall perform or review the calculation measurements made pursuant to 105 CMR 120.564(A), 105 CMR 120.564(B), or 105 CMR 120.564(C).

(E) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with paragraphs 105 CMR 120.564(A), 105 CMR 120.564(B), and 105 CMR 120.564(C).

(F) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.5??.

(G) A licensee shall retain a record of decay calculations required by 105 CMR 120.564(E) in accordance with 105 CMR 120.5??..

~~(A) Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.~~

~~(B) A licensee shall make a record of brachytherapy source utilization which includes:~~

~~(1) The names of the individuals permitted to handle the sources;~~

~~(2) The number and activity of sources removed from storage, the room number of use or patient's or human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and,~~

~~(3) The number and activity of sources returned to storage, the room number of use or patient's or human research subject's~~

~~name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.~~

~~(C) Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.~~

~~(D) A licensee shall maintain the records required in 105 CMR 120.546(B) and (C) for three years.~~

120.565: Therapy-related Computer Systems

The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(C) The accuracy of isodose plots and graphic displays; and

(D) The accuracy of the software used to determine radioactive source positions from radiographic images.

120.566: Training for Use of Manual Brachytherapy Sources

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 105 CMR 120.559 to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.566(B) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or

(B)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(a) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and,

4. Radiation biology; and,

(b) 500 hours work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.566 or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Checking survey meters for proper operation;

3. Preparing, implanting, and removing brachytherapy sources;

4. Maintaining running inventories of material on hand;

5. Using administrative controls to prevent a misadministration involving the use of radioactive material;

6. Using emergency procedures to control radioactive material; and

(2) Three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 105 CMR 120.566 or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.566(B)(1)(b); and,

(3) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.566 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.566(B)(1) and 120.566(B)(2) and has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under 105 CMR 120.559.

120.567: Training for Ophthalmic Use of Strontium-90

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under 105 CMR 120.559 to be a physician who:

(A) Is an authorized user under 105 CMR 120.566 or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(B)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and,

(d) Radiation biology; and,

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user who meets the requirements in 105 CMR 120.566 or 120.567, and that includes the use of strontium-90 for ophthalmic treatment of five individuals that includes:

(a) Examination of each individual to be treated;

(b) Calculation of the dose to be administered;

(c) Administration of the dose; and,

(d) Follow-up and review of each individual's case history; and,

(3) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.566 or 120.567 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.567(B)(1) and 120.567(B)(2) and has achieved a level of competency sufficient to independently function as an authorized user of strontium-90 for ophthalmic use

Sealed Sources For Diagnosis

~~120.547: Release of Patients or Human Research Subjects Treated With Temporary Implants~~

~~(A) Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.~~

~~(B) A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with 105 CMR 120.547(A) for three years. Each record shall include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as microsieverts (mrems) per hour and measured within one meter from the patient or human research subject, and the initials of the individual who made the survey.~~

~~120.548: Possession of Survey Instruments~~

~~A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 1000 microsieverts (100 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsieverts (one mrem) per hour to ten microsieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with 105 CMR 120.518.~~

120.568 ~~41~~: Use of Sealed Sources for Diagnosis

A licensee shall use only ~~the following~~ sealed sources for diagnostic medical uses ~~in accordance with the manufacturer's radiation safety and handling instructions~~:

(A) Approved in the Sealed Source and Device Registry; and,

(B) Handled in accordance with the manufacturer's radiation safety instructions.

~~(A) Iodine-125 as a sealed source in a device for bone mineral analysis;~~

~~(B) Americium-241 as a sealed source in a device for bone mineral analysis;~~

~~(C) Gadolinium-153 as a sealed source in a device for bone mineral analysis or in a portable device for imaging; and,~~

~~(D) Iodine-125 as a sealed source in a portable device for imaging.~~

120.569: Training for Use of Sealed Sources for Diagnosis

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a dagnostic sealed source for use in a device authorized under 105 CMR 120.568 to be a physician, dentist, or podiatrist who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.569(B) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or

(B) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of device that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and,

(4) Radiation biology; and,

(5) Training in the use of the device for the uses requested.

~~120.542: Availability of Survey Instrument~~

~~A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 1000 microsieverts (100 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsieverts (one mrem) per hour to ten millisieverts (1000 mrems) per hour. The instrument shall be operable and calibrated in accordance with 105 CMR 120.518.~~

Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

120.570 ~~49~~: ~~Use of a Sealed Source in a Teletherapy Unit~~ Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

A licensee shall use ~~cobalt-60 or cesium-137 as sealed souces in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions~~ sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic units for therapeutic medical uses:

(A) As approved in the Sealed Source and Device Registry; or

(B) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 105 CMR 120.523(A) are met.

120.571: Surveys of Patients and Human Research Subjects treated with Remote Afterloader unit

(A) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

(B) A licensee shall retain a record of the surveys in accordance with 105 CMR 120.5??.

120.572 ~~50~~: Installation, Maintenance, Adjustment, and Repair ~~Restrictions~~

(A) Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, ~~to perform~~ teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) drive unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s). ~~maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels~~.

(B) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, an Agreement State, Licensing State or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(C) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, an Agreement State, Licensing State or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(D) A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 105 CMR 120.5??.

120.573: Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(A) A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or is unattended;

(2) Permit only individuals approved by authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and,

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(b) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and,

(c) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(B) A copy of the procedures required by 105 CMR 120 573(A)(4) must be physically located at the unit console.

(C) A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by 105 CMR 120 573(A)(4); and,

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(D) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual''s assigned duties, in:

(1) The procedures identified in 105 CMR 120 573(A)(4); and,

(2) the operating procedures for the unit.

(E) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(F) A licensee shall retain a record of individuals receiving instruction required by 105 CMR 120.573(D), in accordance with 105 CMR 120.5??.

120.574: Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(A) A licensee shall control access to the treatment room by a door at each entrance.

(B) A licensee shall equip each entrance to the treatment room with an electical interlock system that will:

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded promptly when an entrance door is opened; and,

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(C) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(D) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(E) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(F) In addition to the requirements specified in 105 CMR 120.574(A) through 105 CMR 120.574(E), a licensee shall:

(1) For [low dose-rate,] medium dose-rate, and pulsed dose-rate remote afterloader units, require:

(a) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and,

(b) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require:

(a) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and,

(b) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

(G) A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:

(1) Remains in the unshielded position; or

(2) Lodges within the patient following completion of the treatment.

120.575: Dosimetry Equipment

(A) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(B) The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 105 CMR 120.575(A). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 105 CMR 120.575(A).

(C) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with 105 CMR 120.5??.

~~120.551: Amendments~~

~~In addition to the requirements specified in 105 CMR 120.504, a licensee shall apply for and receive a license amendment~~

before:

(A) Making any change in the treatment room shielding;

(B) Making any change in the location of the teletherapy unit within the treatment room;

(C) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(D) Relocating the teletherapy unit; or,

(E) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

120.552: Safety Instruction

(A) A licensee shall post written instructions at the teletherapy unit console. These instructions shall inform the operator of:
(1) The procedure to be followed to ensure that only the patient or human research subject is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;
(2) The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and,
(3) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(B) A licensee shall provide instruction in the topics identified in 105 CMR 120.552(A) to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year.

(C) A licensee shall maintain a record of individuals receiving instruction required by 105 CMR 120.552(B), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

120.553: Doors, Interlocks, and Warning Systems

(A) A licensee shall control access to the teletherapy room by a door at each entrance.

(B) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:
(1) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;
(2) Turn the beam of radiation "off" immediately when an entrance door is opened; and,
(3) Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(C) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

120.554: Possession of Survey Instrument

A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 1000 microsieverts

~~(100 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsieverts (one mrem) per hour to ten millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with 105 CMR 120.518.~~

~~120.555: Radiation Monitoring Device~~

~~(A) A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.~~

~~(B) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.~~

~~(C) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.~~

~~(D) A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.~~

~~(E) A licensee shall maintain a record of the check required by 105 CMR 120.555(D) for three years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.~~

~~(F) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 105 CMR 120.555(E).~~

~~(G) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.~~

~~120.556: Viewing System~~

~~A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.~~

~~120.557: Dosimetry Equipment~~

~~(A) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:~~

~~(1) The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration; or,~~

~~(2) The system shall have been calibrated within the previous four years; 18 to 30 months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2%. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a~~

~~cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.~~

~~(B) The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 105 CMR 120.557(A). This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system shall be the same system used to meet the requirement in 105 CMR 120.557(A).~~

~~120.557: continued~~

~~(C) The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 105 CMR 120.557(A) and (B), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.~~

120.576~~58~~: Full Calibration Measurements on Teletherapy Units

(A) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit; and,

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and,

(c) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and,

(3) At intervals not exceeding one year.

(B) To satisfy the requirement of 105 CMR 120.576~~58~~(A), full calibration measurements shall include determination of:

(1) The output within three percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy;

(5) "On-off" error; and,

(6) The accuracy of all distance measuring and localization devices in medical use.

(C) A licensee shall use the dosimetry system described in 105 CMR 120.575~~57~~ to measure the output for one set of exposure conditions. The remaining radiation measurements required in 105 CMR 120.576~~58~~(B)(1) may then be made using a dosimetry system that indicates relative dose rates.

(D) A licensee shall make full calibration measurements required by 105 CMR 120.576~~58~~(A) in accordance with published protocols accepted by nationally recognized bodies. ~~the measurements required for annual calibration by *Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40*, Medical Physics, Vol. 21, No. 4, 1994, pp. 581-618.~~

(E) A licensee shall correct mathematically the outputs determined in 105 CMR 120.576 ~~58~~(B)(1) for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137, or at intervals consistent with 1% decay for all other nuclides.

(F) Full calibration measurements required by 105 CMR 120.576~~58~~(A) and ~~P~~ physical decay corrections required by 105 CMR 120.576~~58~~(E) shall be performed by ~~a teletherapy~~ the authorized medical physicist. ~~named on the licensee's license or authorized~~

~~by a license issued by the NRC or an Agreement State to perform such services.~~

(G) A licensee shall retain ~~maintain~~ a record of each calibration in accordance with 105 CMR 120.5??. ~~for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.~~

120.577: Full Calibration Measurements on Remote Afterloader Units

(A) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit; and,

(2) Before medical use under the following conditions:

(a) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and,

(b) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and,

(3) At intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days.; and,

(4) At intervals not exceeding one year for low dose-rate remote afterloader units.

(B) To satisfy the requirement of 105 CMR 120.577(A), full calibration measurements shall include, as applicable, determination of:

(1) the output within +/- 5%;

(2) Source position accuracy to within +/- 1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of applicators; and,

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(C) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in 105 CMR 120.577(B), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(D) A licensee shall use the dosimetry system described in 105 CMR 120.575(A) to measure the output.

(E) A licensee shall make full calibration measurements required by 105 CMR 120.577(A) of this section in accordance with published protocols accepted by nationally recognized bodies.

(F) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 105 CMR 120.577(A) through 105 CMR 120.577(E).

(G) A licensee shall mathematically correct the outputs determined in 105 CMR 120.577(B)(1) for physical decay at intervals consistent with 1 percent physical decay.

(H) Full calibration measurements required by 105 CMR 120.577(A) and physical decay corrections required by 105 CMR 120.577(G) must be performed by the authorized medical physicist.

(I) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.5??

120.578: Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units

(A) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit; and,

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and,

(c) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and,

(3) At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(B) To satisfy the requirement of 105 CMR 120.578(A), full calibration measurements shall include determination of:

(1) The output within +/- 3%;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitchs;

(9) Emergency timing circuits; and,

(10) Stereotactic frames and localizing devices (trunnions).

(C) A licensee shall use the dosimetry system described in 105 CMR 120.575(A) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 105 CMR 120.578(B)(1) may be made using a dosimetry system

that indicates relative dose rates.

(D) A licensee shall make full calibration measurements required by 105 CMR 120.578(A) in accordance with published protocols accepted by nationally recognized bodies.

(E) A licensee shall mathematically correct the outputs determined in 105 CMR 120.578(B)(1) at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(F) Full calibration measurements required by 105 CMR 120.578(A) and physical decay corrections required by 105 CMR 120.578(E) must be performed by the authorized medical physicist.

(G) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.5??

120.5795~~9~~: Periodic Spot-Checks for Teletherapy Units

(A) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of: ~~at intervals not to exceed one month.~~

~~(B) To satisfy the requirement of 105 CMR 120.559(A), spot-checks shall include determination of:~~

(1) Timer accuracy, ~~constancy~~ and timer linearity over the range of use;

(2) "On-off" error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions; and,

(6) The difference between the measurement made in 105 CMR 120.5795~~9~~(A ~~B~~)(5) and the anticipated output, expressed as a percentage of the anticipated output (*i.e.*, the value obtained at last full calibration corrected mathematically for physical decay).

~~(C) A licensee shall use the dosimetry system described in 105 CMR 120.557 to make the spot-check required in 105 CMR 120.559(B)(5).~~

(B ~~D~~) A licensee shall perform measurements ~~spot-check~~s required by 105 CMR 120.579 ~~59~~(A) in accordance with procedures established by the authorized medical ~~teletherapy~~ physicist. That individual ~~The teletherapy physicist does not~~ need not ~~to~~ actually perform the output spot-check measurements.

(C~~E~~) A licensee shall have the authorized medical ~~teletherapy~~ physicist review the results of each output spot-check within 15 days. The authorized medical ~~teletherapy~~ physicist shall promptly notify the licensee in writing of the results of each output spot-check. ~~The licensee shall keep a copy of each written notification for three years.~~

(D~~F~~) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of: ~~at intervals not to exceed one month.~~

~~(G) To satisfy the requirement of 105 CMR 120.559(F), safety spot-checks shall assure proper operation of:~~

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism);

(3) Source exposure ~~Beam condition~~ indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and,

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned ~~"~~off~~"~~.

(E ~~H~~) If the results of the checks required in 105 CMR 120.579(D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. ~~A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the Agency~~.

(F) A licensee shall retain a record of each spot-check required by 105 CMR 120.579(A) and 105 CMR 120.579(D), in accordance with 105 CMR 120.5??.

~~(I) A licensee shall promptly repair any system identified in 105 CMR 120.559(G) that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.~~

~~(J) A licensee shall maintain a record of each spot-check required by 105 CMR 120.559(A) and (F) for three years. The record shall include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit, and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the measured timer accuracy, the calculated "on-off" error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.~~

120.580: Periodic Spot-Checks for Remote Afterloader Units

(A) A licensee authorized to use remote afterloader units for medical use shall perform spot-checks on each remote afterloader facility and on each unit:

(1) At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;
(2) Prior to each patient treatment with a low dose-rate remote afterloader unit; and,
(3) After each source installation.

(B) A licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in 105 CMR 120.580(A) The authorized medical physicist need not actually perform the spot-check measurements.

(C) A licensee shall have the authorized medical physicist review the results of each output spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each output spot-check.

(D) To satisfy the requirement of 105 CMR 120.580(A), spot-checks must, at a minimum, assure proper operation of:
(1) Electrical interlocks at each remote afterloader unit room entrance;
(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
(3) Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
(4) Emergency response equipment;
(5) Radiation monitors used to indicate the source position;
(6) Timer accuracy;
(7) Clock (date and time) in the unit's computer; and,
(8) Decayed source(s) activity in the unit's computer.

(E) If the results of the checks required in 105 CMR 120.580(D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(F) A licensee shall retain a record of each spot-check required by 105 CMR 120.580(D), in accordance with 105 CMR

120.5??.

120.581: Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units

(A) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks on each gamma stereotactic radiosurgery facility and on each unit:

(1) Monthly;
(2) At the beginning of each day of use; and,
(3) After each source installation.

(B) A licensee shall have the authorized medical physicist:

(1) Establish written procedures for performing the spot-checks required in 105 CMR 120.581(A); and,

(2) Review the results of each spot-check required by 105 CMR 120.581(A)(1) within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spot check.

(C) To satisfy the requirement of 105 CMR 120.581(A)(1), spot-checks must, at a minimum:
(1) Assure proper operation of:

(a) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(b) Helmet microswitchs;

(c) Emergency timing circuits; and,

(d) Stereotactic frames and localizing devices (trunnions).

(2) Determine:

(a) The output for one typical set of operating conditions measured with the dosimetry system described in 105 CMR 120.575(B);

(b) The difference between the measurement made in 105 CMR 120.581(C)(2)(a) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(c) Source output against computer calculation;

(d) Timer accuracy and linearity over the range of use;

(e) On-off error; and,

(f) Trunnion centricity.

(D) To satisfy the requirements of 105 CMR 120.581(A)(2) and 105 CMR 120.581(A)(3), spot-checks must assure proper operation of:

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposure; and,

(6) Emergency off buttons.

(E) A licensee shall arrange for prompt repair of any system identified in 105 CMR 120.581(C) that is not operating properly.

(F) If the results of the checks required in 105 CMR 120.581(D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(G) A licensee shall retain a record of each check required by 105 CMR 120.581(C) and 105 CMR 120.581(D) in accordance with 105 CMR 120.5??.

120.582: Additional Technical Requirements for Mobile Remote Afterloader Units

(A) A licensee providing mobile remote afterloader service shall:

(1) Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and,

(2) Account for all sources before departure from a client's address of use.

(B) In addition to the periodic spot-checks required by 105 CMR 120.580, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of :

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and,

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(C) In addition to the requirements for checks in 105 CMR 120.582(B), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(D) If the results of the checks required in 105 CMR 120.582(B) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(E) A licensee shall retain a record of each check required by 105 CMR 120.582(B) in accordance with 105 CMR 120.5??.

120.583: Radiation Surveys

(A) In addition to the survey requirements in 105 CMR 120.225 of these regulations, a person licensed pursuant to 105 CMR 120.500 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.

(B) The licensee shall make the survey required by 105 CMR 120.583(A) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(C) A licensee shall retain a record of the radiation surveys required in 105 CMR 120.583(A) in accordance with 105 CMR 120.5??.

~~120.560: Radiation Surveys for Teletherapy Facilities~~

~~(A) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by 105 CMR 120.551, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with 120.518 to verify that:~~

~~(1) The maximum and average radiation levels at one meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 100 microsieverts (10 mrems) per hour and 20 microsieverts (two mrems) per hour, respectively; and,~~

~~(2) With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:~~

~~(a) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 105 CMR 120.200; and,~~

~~(b) Radiation levels in unrestricted areas do not exceed the limits specified in 105 CMR 120.200.~~

~~(B) If the results of the surveys required in 105 CMR 120.560(A) indicate any radiation levels in excess of the respective limit~~

specified in 105 CMR 120.560(A), the licensee shall lock the control in the "off" position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or,

(2) Until the licensee has received a specific exemption from the Agency.

(C) A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts (mrems) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

120.561: Safety Spot-Checks for Teletherapy Facilities

(A) A licensee shall promptly spot-check all systems listed in 105 CMR 120.559(G) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 105 CMR 120.551.

(B) If the results of the spot-checks required in 105 CMR 120.561(A) indicate the malfunction of any system specified in 105 CMR 120.559, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

~~120.561: continued~~

~~(C) A licensee shall maintain a record of the facility checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the Radiation Safety Officer.~~

~~120.562: Modification of Teletherapy Unit or Room Before Beginning a Treatment Program~~

~~If the survey required by 105 CMR 120.560 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 105 CMR 120.200, before beginning the treatment program the licensee shall:~~

~~(A) Either equip the unit with stops or add additional radiation shielding to ensure compliance with 105 CMR 120.200;~~

~~(B) Perform the survey required by 105 CMR 120.560 again; and,~~

~~(C) Include in the report required by 105 CMR 120.563 the results of the initial survey, a description of the modification made to comply with 105 CMR 120.562(A), and the results of the second survey; or,~~

~~(D) Request and receive a license amendment under 105 CMR 120.200 that authorizes radiation levels in unrestricted areas greater than those permitted by 105 CMR 120.200.~~

~~120.563: Reports of Teletherapy Surveys, Checks, Tests and Measurements~~

~~A licensee shall furnish a copy of the records required in 105 CMR 120.560, 120.561, 120.562 and the output from the teletherapy source expressed as grays (rads) per hour at one meter from the source and determined during the full calibration required in 105 CMR 120.558 to the Agency within 30 days following completion of the action that initiated the record requirement.~~

120.5846~~4~~: Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units

(A) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during ~~teletherapy~~ source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(B) This inspection and servicing may ~~shall~~ only be performed by persons specifically licensed to do so by the Agency, an Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission.

(C) A licensee shall maintain a record of the inspection and servicing in accordance with 105 CMR 120.5??. ~~for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.~~

120.585: Therapy-Related Computer Systems

The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(C) The accuracy of isodose plots and graphic displays;

(D) The accuracy of the software used to determine radioactive source positions from radiographic images; and,

(E) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

120.587: Training for Use of Remote Afterloader units, Teletherapy units, and Gamma stereotactic Radiosurgery Units

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a sealed source for a use authorized under 105 CMR 120.570 to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.587(B) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or

(B) (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(a) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and,

5. Radiation biology; and,

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.587 or equivalent Agreement State or Nuclear Regulatory Commission requirements at a medical institution, involving:

1. Reviewing full calibration measurements and periodic spot checks;

2. Preparing treatment plans and calculating treatment doses and times;

3. Using administrative controls to prevent a misadministration involving the use of radioactive material;

4. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(2) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 105 CMR 120.587 or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.587(B)(1)(b); and,

(3) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.587, equivalent Agreement State or Nuclear Regulatory requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.587(B)(1) and 105 CMR 120.587(B)(2) and has achieved a level of competency sufficient to independently function as an authorized user of the therapeutic medical unit for which the individual is requesting authorized user status.

Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

120.589: Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in 105 CMR 120.500 if:

(A) The applicant or licensee has submitted the information required by 105 CMR 120.507(B), 120.507(C) and 120.507(D); and,

(B) The applicant or licensee has received written approval from the Agency in a license and uses the material in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the material.

~~120.565: Radiation Safety Officer~~

~~Except as provided in 105 CMR 120.566, an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in 105 CMR 120.507 shall:~~

~~(A) Be certified by the:~~
~~(1) American Board of Health Physics in Comprehensive Health Physics; or~~
~~(2) American Board of Radiology; or~~
~~(3) American Board of Nuclear Medicine; or~~
~~(4) American Board of Science in Nuclear Medicine; or~~
~~(5) The American Board of Medical Physicists in Radiation Oncology Physics; or~~
~~(6) Board of Pharmaceutical Specialties in Nuclear Pharmacy; or~~
~~(7) Royal College of Physicians and Surgeons of Canada in Nuclear Medicine; or~~
~~(8) American Osteopathic Board of Radiology; or~~
~~(9) American Osteopathic Board of Nuclear Medicine; or,~~

~~(B) Have had 200 hours of classroom and laboratory training covering:~~

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity;
(4) Radiation biology; and,
(5) Radiopharmaceutical chemistry; and,
(6) Have had one year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an Agency, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or,

(C) Be an authorized user for those radioactive material uses that come within the Radiation Safety Officer's responsibilities.

120.566: Training for Experienced Radiation Safety Officer

An individual identified as a Radiation Safety Officer on an Agency, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license on March 11, 1994 who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of 105 CMR 120.565.

120.567: Training for Uptake, Dilution, or Excretion Studies

Except as provided in 105 CMR 120.575 and 120.576, the licensee shall require the authorized user of a radiopharmaceutical listed in 105 CMR 120.531 to be a physician who:

(A) Is certified in:
(1) Nuclear medicine by the American Board of Nuclear Medicine; or
(2) Diagnostic radiology by the American Board of Radiology; or
(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
(4) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or
(5) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or,

(B) Has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience.
(1) To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:
(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity;
(d) Radiation biology; and,
(e) Radiopharmaceutical chemistry.
(2) To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:
(a) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
(b) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
(c) Administering dosages to patients or human research subjects and using syringe radiation shields;
(d) Collaborating with the authorized user in the interpretation of radionuclide test results; and,
(e) Patient or human research subject follow-up; or,
(C) Has successfully completed a six month training program in nuclear medicine as part of a training program that has been

approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 105 CMR 120.567(B).

120.568: Training for Imaging and Localization Studies

Except as provided in 105 CMR 120.575 or 120.576, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in 105 CMR 120.533 to be a physician who:

(A) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine; or,

(2) Diagnostic radiology by the American Board of Radiology; or,

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or,

(4) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or,

(5) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or,

(B) Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Radiopharmaceutical chemistry; and,

(e) Radiation biology.

(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(c) Calculating and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent the misadministration of radioactive material;

(e) Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and,

(f) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(3) To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(a) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

(b) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(c) Administering dosages to patients or human research subjects and using syringe radiation shields;

(d) Collaborating with the authorized user in the interpretation of radionuclide test results; and,

(e) Patient or human research subject follow-up; or,

(C) Has successfully completed a six month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training,

~~work experience, and supervised clinical experience in all the topics identified in 105 CMR 120.568(B).~~

120.569: Training for Therapeutic Use of Radiopharmaceuticals

Except as provided in 105 CMR 120.575, the licensee shall require the authorized user of a radiopharmaceutical pursuant to 105 CMR 120.537 for therapy to be a physician who:

(A) Is certified in:

(1) Nuclear medicine by The American Board of Nuclear Medicine; or,

(2) Radiation oncology, therapeutic radiology, or radiology by The American Board of Radiology; or,

(3) Nuclear medicine or radiation oncology by the American Osteopathic Board of Radiology after 1984; or,

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or,

(B) Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.

(1) To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and,

(d) Radiation biology;

(2) To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include at least five treatment cases for each procedure with radiation safety hazards similar to that use for which the individual is requesting authorized user status.

120.570: Training for Therapeutic Use of Brachytherapy Sources

Except as provided in 105 CMR 120.575, the licensee shall require the authorized user using a brachytherapy source specified in 105 CMR 120.543 for therapy to be a physician who:

(A) Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology; or,

(2) Radiation oncology by the American Osteopathic Board of Radiology; or,

(3) Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or,

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or,

(B) Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and,

(d) Radiation biology.

(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

~~(b) Checking survey meters for proper operation;~~

~~(c) Preparing, implanting, and removing sealed sources;~~

~~(d) Using administrative controls to prevent the misadministration of radioactive material; and,~~

~~(e) Using emergency procedures to control radioactive material.~~

120.570: continued

(3) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

(a) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(b) Selecting the proper brachytherapy sources, dose, and method of administration;

(c) Calculating the dose; and,

(d) Post-administration follow-up and review of case histories in collaboration with the authorized user.

120.571: Training for Ophthalmic Use of Strontium-90

Except as provided in 105 CMR 120.575, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

(A) Is certified in radiology or therapeutic radiology by the American Board of Radiology; or,

(B) Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

(1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and,

(d) Radiation biology.

(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

(a) Examination of each individual to be treated;

(b) Calculation of the dose to be administered;

(c) Administration of the dose; and,

(d) Follow-up and review of each individual's case history.

120.572: Training for Use of Sealed Sources for Diagnosis

Except as provided in 105 CMR 120.575, the licensee shall require the authorized user using a sealed source in a device specified in 105 CMR 120.541 to be a physician, dentist, or podiatrist who:

(A) Is certified in:

(1) Radiology, diagnostic radiology with special competence in nuclear radiology, or therapeutic radiology by the American Board of Radiology; or,

(2) Nuclear medicine by the American Board of Nuclear Medicine; or,

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or,

~~(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or,~~

~~(B) Has completed eight hours of instruction in basic radionuclide handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training shall include:~~

120.572: continued

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
(2) Radiation biology; and,
(3) Radiation protection and training in the use of the device for the purposes authorized by the license.

120.573: Training for Teletherapy

Except as provided in 105 CMR 120.575, the licensee shall require the authorized user of a sealed source specified in 105 CMR 120.549 in a teletherapy unit to be a physician who:

(A) Is certified in:
(1) Radiology or therapeutic radiology by the American Board of Radiology; or,
(2) Radiation oncology by the American Osteopathic Board of Radiology; or,
(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or,
(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or,

(B) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.
(1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:
(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity; and,
(d) Radiation biology.
(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:
(a) Review of the full calibration measurements and periodic spot checks;
(b) Preparing treatment plans and calculating treatment times;
(c) Using administrative controls to prevent misadministrations;
(d) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and,
(e) Checking and using survey meters.
(3) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:
(a) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
(b) Selecting the proper dose and how it is to be administered;
(c) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and,
(d) Post-administration follow-up and review of case histories.

~~120.574: Training for Teletherapy Physicist~~

~~The licensee shall require the teletherapy physicist to:~~

~~(A) Be certified by the American Board of Radiology in:~~
~~(1) Therapeutic radiological physics;~~
~~(2) Roentgen-ray and gamma-ray physics;~~
~~(3) X-ray and radium physics; or,~~
~~(4) Radiological physics; or,~~

120.574: continued

(B) Be certified by the American Board of Medical Physics in radiation oncology physics; or,

(C) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 105 CMR 120.521, 120.558, 120.558 and 120.560 under the supervision of a teletherapy physicist during the year of work experience.

120.575: Training for Experienced Authorized Users

Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an Agency or [NRC or Agreement State or Licensing State] license on March 11, 1995 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of 105 CMR 120.565 through 120.577.

120.576: Physician Training in a Three-Month Program

A physician who, before July 1, 1984, began a three-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of 105 CMR 120.567 or 120.568.

120.577: Recentness of Training

The training and experience specified in 105 CMR 120.565 through 120.574 shall have been obtained within the seven years preceding the date of application or the individual shall have had continuing applicable experience since the required training and experience was completed.

120.580: Training for an Authorized Nuclear Pharmacist

The licensee shall require the authorized nuclear pharmacist to be a pharmacist as defined in 105 CMR 120.005 who:

(A) has current board certification as nuclear pharmacist by the Board of Pharmaceutical Specialties, or,

(B) (1) has completed 700 hours in a structured educational program consisting of both:

(a) didactic training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and,
5. Radiation biology; and,

(b) supervised experience in a nuclear pharmacy involving the following:

1. Shipping, receiving, and performing related radiation surveys;
2. Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;

~~4. Using administrative controls to avoid mistakes in the administration of radioactive material;~~

~~5. Using procedures to prevent or minimize contamination and using proper decontamination procedures; and,~~

~~(2) has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.~~

~~120.581: Training for Experienced Nuclear Pharmacist~~

~~A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in 105 CMR 120.580(B)(1) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement of 105 CMR 120.580(B)(2) and recentness of training in 105 CMR 120.577.~~

Records

120. 590: Requirements for Record Keeping

(A) Records of Authority and Responsibilities for Radiation Protection Programs.

(1) A licensee shall retain a record of actions taken by the licensee's management in accordance with 105 CMR 120.515(A) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(2) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by 105 CMR 120.515(D), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 105 CMR 120.515(B) The record must include the signature of the Radiation Safety Officer and licensee management.

(B) Records of Radiation Protection Program Safety Changes.

A licensee shall retain a record of each radiation protection program change made in accordance with 105 CMR 120.517(A) for five years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

(C) Records of Written Directives

A licensee shall retain a copy of each written directive as required by 105 CMR 120.521 for three years.

(D) Records of Medical Events.

A licensee shall retain a record of medical events reported in accordance with 105 CMR 120.594(A) for three years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the medical event; medical event a brief description of

the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(E) Record of a Dose to an Embryo/Fetus or a Nursing Child.

A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with 105 CMR 120.594(B) for three years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned of the embryo/fetus or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.]

(F) Records of calibrations of instruments used to measure the activity of unsealed radioactive material.

A licensee shall maintain a record of instrument calibrations required by 105 CMR 120.536(B) for three years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(G) Records of Survey Instrument Calibrations. A licensee shall maintain a record of instrument calibrations required by 105 CMR 120.533 for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(H) Records of Dosages of Unsealed Radioactive Material for Medical Use. A licensee shall maintain a record of dosage determinations required by 105 CMR 120.534 for three years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 µCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

(I) Records of Possession of Sealed Sources and Brachytherapy Sources.

(1) A licensee shall retain a record of the leak test required by 105 CMR 120.536(B) for three years. The record must contain the model number, and serial number if one has been assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the results of the test, the date of the test, and the name of the individual who performed the test.

(2) A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 105 CMR 120.536(E) for three years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(J) Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by 105 CMR 120.539 for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(K) Records of the release of individuals containing radioactive drugs or implants containing radioactive material.

(1) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(a) Using the retained activity rather than the activity administered;

(b) Using an occupancy factor less than 0.25 at 1 meter;

(c) Using the biological or effective half-life; or

(d) Considering the shielding by tissue.

(2) A licensee shall retain a record, for three years after the date of release, that the instructions required by 105 CMR 120.540(B) were provided to a breast-feeding woman [if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem)].

(L) Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.

(1) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by 105 CMR 120.541(A)(1), for three years after the last provision of service.

(2) A licensee shall retain the record of each survey required by 105 CMR 120.541(A)(4) for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(M) Records of Decay-in-Storage A licensee shall maintain records of the disposal of licensed materials, as required by 105 CMR 120.543, for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(N) Records of Radionuclide Purity. A licensee shall maintain a record of the radionuclide contaminant concentration tests required by 105 CMR 120.548 for three years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

(P) Records of Safety Instruction and Training. A licensee shall maintain a record of safety instructions and training required by 105 CMR 120.553, 105 CMR 120.562 and 105 CMR 120.573 for three years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(Q) Records of Radiation Surveys of Patients and Human Research Subjects. A licensee shall maintain a record of the surveys required by 105 CMR 120.560 and 105 CMR 120.571 for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

120. 592: Requirements for Record Keeping pertaining to the use of Sealed Sources

(A) Records of brachytherapy source inventory.

(1) A licensee shall maintain a record of brachytherapy source accountability required by 105 CMR 120.561 for three years.

(2) For temporary implants, the record must include:

(a) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(b) The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them from storage.

(3) For permanent implants, the record must include:

(a) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(b) The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

(c) The number and activity of sources permanently implanted in the patient or human research subject.

(B) Records of Calibration Measurements on Brachytherapy Sources. A licensee shall maintain a record of the calibrations on brachytherapy sources required by 105 CMR 120.564 for three years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(C) Records of Decay of Strontium-90 Sources for Opthalmic Treatments. A licensee shall maintain a record of the activity of a strontium-90 source required by 105 CMR 120.564. The record must include the date and initial activity of the source as determined under 105 CMR 120.564, and for each decay calculation, the date and the source activity.

(D) Records of Installation, Maintenance, Adjustment, and Repair. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by 105 CMR 120.572 for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(E) Records of Dosimetry Equipment.

(1) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 105 CMR 120.575 for the duration of the license.

(2) For each calibration, intercomparison, or comparison, the record must include:

(a) The date;

(b) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 105 CMR 120.575(A) and 105 CMR 120.575(B);

(c) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(d) The names of the individuals who performed the calibration, intercomparison, or comparison.

(F) Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.

(1) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by 105 CMR 120.576, 105 CMR 120.577 and 105 CMR 120.578 for three years.

(2) The record must include:

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;

(c) The results and assessments of the full calibrations;

(d) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(e) The signature of the authorized medical physicist who performed the full calibration.

(G) Records of Periodic Spot-Checks for Teletherapy Units.

(1) A licensee shall retain a record of each periodic spot-check for teletherapy units required by 105 CMR 120.579 for three years.

(2) The record must include:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(c) An assessment of timer linearity and constancy;

(d) The calculated on-off error;

(e) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(f) The determined accuracy of each distance measuring and localization device;

(g) The difference between the anticipated output and the measured output;

(h) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(H) Records of Periodic Spot-Checks for Remote Afterloader Units.

(A) A licensee shall retain a record of each spot-check for remote afterloader units required by 105 CMR 120.580 for three years.

(B) The record must include, as applicable:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(I) Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by 105 CMR 120.581 for three years.

(2) The record must include:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(c) An assessment of timer linearity and accuracy;

(d) The calculated on-off error;

(e) A determination of trunnion centricity;

(f) The difference between the anticipated output and the measured output;

(g) An assessment of source output against computer calculations;

(h) Notations indicating the operability of radiation monitors, helmet microswitchs, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(J) Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

(1) A licensee shall retain a record of each check for mobile remote afterloader units required by 105 CMR 120.582 for three years.

(2) The record must include:

(a) The date of the check;

(b) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(c) Notations accounting for all sources before the licensee departs from a facility;

(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and

(e) The signature of the individual who performed the check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(K) Records of Surveys of Therapeutic Treatment Units.

(1) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with 105 CMR 120.583 for the duration of use of the unit.

(2) The record must include:

(a) The date of the measurements;

(b) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(d) The signature of the individual who performed the test.

(L) Records of 5-Year Inspection for Teletherapy and Gamma Stereotactic Surgery Units.

(1) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by 105 CMR 120.584 for the duration of use of the unit.

(2) The record must contain:

(a) The inspector's radioactive materials license number;

(b) The date of inspection;

(c) The manufacturer's name and model number and serial number of both the treatment unit and source;
(d) A list of components inspected and serviced, and the type of service; and

(f) The signature of the inspector.

Reports

120.594: Reports and Notifications

(A) Reports and Notifications of Medical Events.

(1) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in:

(a) A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either

1. The total dose delivered differs from the prescribed dose by 20 percent or more;

2. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or

3. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(b) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

1. An administration of a wrong radioactive drug;

2. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

3. An administration of a dose or dosage to the wrong individual or human research subject;

4. An administration of a dose or dosage delivered by the wrong mode of treatment; or

5. A leaking sealed source.

(c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(2) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the medical event.

(4) The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.

(a) The written report must include:

1. The licensee's name;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

5. The effect, if any, on the individual(s) who received the administration;

6. Actions, if any, that have been taken, or are planned, to prevent recurrence;

7. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(5) The licensee shall provide notification of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment,

telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event or to that individual's responsible relatives or guardians.

(7) A licensee shall retain a record of a medical event in accordance with 105 CMR 120.590(D). A copy of the record required under 105 CMR 120.590(D) shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the medical event.

(B) Report and Notification of a Dose to an Embryo/fetus or a nursing child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

(a) Is greater than 5 mSv (500 mrem) total effective dose equivalent; or

(b) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2) in this section.

(4) The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2).

(a) The written report must include:

1. The licensee's name;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

5. The effect on the embryo/fetus or the nursing child;

6. What actions, if any, have been taken, or are planned, to prevent recurrence; and

7. Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(b) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after of discovery of an event that would require reporting under 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the misadministration, event because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the misadministration event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with 105 CMR 120.590(E). A copy of the record required under 105 CMR 120.590(E) shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

(C) Reports of Leaking Sources.

A licensee shall file a report with the Agency within five days if a leakage test required by 105 CMR 120.536 reveals the presence of 185 Becquerel (0.005 μCi) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

(D) Reports of Patient Departure Prior to Authorized Release.

(1) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under 105 CMR 120.540(A).

(2) The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure. The written report must include:

(a) The licensee's name;

(b) The date and time of the unauthorized departure;

(c) The projected date and time when release would have occurred;

(d) The general location address of the patient's or human research subject's home or anticipated destination following departure;

(e) The radionuclide, chemical and physical form and calculated activity at time of release;

(f) The apparent reason(s) for the departure prior to authorized release; and,

(g) A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

(E) Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.

(1) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of 105 CMR 120.221 as a result of the deceased's body.

(2) The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in 105 CMR 120.594(E)(1) has died. The written report must include:

(a) The licensee's name;

(b) The date of death;

(c) The radionuclide, chemical and physical form and calculated activity at time of death; and,

(d) The names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 mSv (500 mrem).